

Amended Exhibit A

SUPPLEMENTAL AND AMENDED ALLEGATIONS TO PLAINTIFFS' CLASS
ACTION COMPLAINT IN SUPPORT OF PLAINTIFF'S MOTION FOR LEAVE
TO AMEND [Doc. 33] in No. 18-op-45985 And [Doc. 5582] in 1:17-md-2804

**THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

Mike Masiowski, M.D. on behalf of himself and all others similarly situated,)	MDL 2804
)	
Plaintiff,)	
)	
AMERISOURCEBERGEN DRUG)	CASE NO. 2:18-CV-2080
CORPORATION; CARDINAL HEALTH,)	SUPPLEMENTAL AND
INC.; McKESSON CORPORATION;)	AMENDED ALLEGATIONS
TEVAPHARMACEUTICAL INDUSTRIES,)	TO PLAINTIFFS' CLASS
LTD.; TEVA PHARMACEUTICALS)	ACTION COMPLAINT
USA, INC.; CEPHALON, INC.;)	
JOHNSON & JOHNSON; JANSSEN)	JURY TRIAL DEMANDED
PHARMACEUTICALS, INC.; ORTHOMCNEIL-)	
JANSSEN PHARMACEUTICALS, INC. n/k/a)	
JANSSEN PHARMACEUTICALS, INC.;)	
JANSSEN PHARMACEUTICA INC. n/k/a)	
JANSSEN PHARMACEUTICALS, INC.;)	
NORAMCO, INC.;)	
ALLERGAN PLC f/k/a ACTAVIS PLS;)	
WATSON PHARMACEUTICALS, INC.)	
n/k/a ACTAVIS, INC.; WATSON)	
LABORATORIES, INC.; ACTAVIS LLC;)	
ACTAVIS PHARMA, INC. f/k/a)	
WATSON PHARMA, INC. CVS HEALTH)	
CORPORATION, THE KROGER COMPANY,)	
WALGREENS BOOTS ALLIANCE, INC.)	
WAL-MART, INC. ALPHA PHARMA)	
SOLUTIONS, SMITH DRUG COMPANY)	
EXPRESS SCRIPTS, OPTUM.)	
)	
Defendants.)	
)	

**PLAINTIFF MICHAEL MASIOWSKI'S CORRECTED PROPOSED FIRST AMENDED
CLASS ACTION COMPLAINT**

Plaintiff, Michael Masiowski M. D. and Simon Clark D.O., are emergency room physicians, on behalf of themselves and all others similarly situated, filed an action in the District of South Carolina, Charleston Division on July 25, 2018, and it was transferred to this Court on July 26, 2018 by the Judicial Panel on Multidistrict Litigation as Case 2:18-CV-2080.

Plaintiffs, brings this Complaint against Defendants Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. McKesson Corporation; Cardinal Health, Inc.; Walmart, Inc., Walgreens Boots Alliance, Inc., Alpha Pharma Solutions, Smith Drug Company, The Kroger Company, CVS Health Corporation, Express Scripts Defendants, Optum Defendants, and AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges, upon information and belief, as follows:

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INTRODUCTION

I. THE OPIOID CRISIS

1. This case is about one thing: corporate greed. Defendants put their desire for profits above the health and well-being of consumers, and emergency room physician health care providers at the cost to Plaintiffs and the putative class of Independent Emergency Room Physicians¹ that he seeks to represent.

2. Independent Emergency Room Physicians is defined as those emergency room physicians that are non-hospital employees and worked in emergency room as defined by EMTALA. It is estimated that approximately 77% of all Emergency Room Doctors are not hospital employees.²

3. Tens of thousands of patients have been treated by independent emergency room physicians because of the “opioid epidemic” throughout the United States.

4. Plaintiffs and the putative class lost millions of dollars each year in providing emergency room health care services to patients who were opioid addicted, had opioid misuse issues, including “pill seeking”, as well as those that were uninsured, were indigent (i.e., lacked resources to pay for the services), or otherwise eligible for services through programs such as Medicaid.

5. Medicaid payments were at below market rates. At times Plaintiffs and the putative class were not compensated at all for services provided by uninsured patients.

¹ Independent Emergency Room Physicians is defined as those emergency room physicians that are non hospital employees and worked in emergency room as defined by EMTALA.

²It is estimated that approximately 77% of all Emergency Room Doctors are not hospital employees. Carol K. Kane,PHD, “Policy Research Perspectives, Updated Data on Physician Practice Arrangements”. American Medical Association, 2019.

Additionally, Plaintiffs and putative class were subjected patient satisfaction ratings and those ratings at times were negative from those denied opioids, impacting Plaintiffs and putative classes wellbeing and reputations.

6. All of these services to be referred to as “Opioid Treatment Services” were necessary for Plaintiffs and the putative class to provide because 1) regardless of whether a patient can pay, they must be provided medical care under prevailing federal and state law for medical and possible psychiatric care, and 2) of the adverse effects to patients from prescription opium painkillers (“opioids”) which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

7. Independent Emergency Room Physicians across the United States are the front-line treatment for victims of the opioid epidemic. Independent Emergency Room Physicians are legally compelled to treat patients with opioid-related conditions and, as a result, have been directly damaged by the epidemic.³ Plaintiffs and the putative class, in essence, have been forced to provide an inordinate amount of emergency room services related to the “opioid epidemic,” either for no compensation or for compensation substantially below market rates due to the unlawful marketing, distribution and sale of opioids. They have also been forced to spend time in training on accepted uses in order to renew necessary licenses or face loss of prescribing abilities.

8. Substance use disorders are a spectrum that range from misuse and abuse of drugs to addiction.⁴ Throughout this Complaint, “addiction” refers to the entire range of substance

³ Emergency Medical Treatment and Labor Act (“EMTALA”), 42 U.S.C. § 1395dd.

⁴ Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) (“DSM-V”).

abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder spectrum.

9. Defendants knew that opioids were effective treatments for only short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew—and had known for years—that opioids were highly addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as “chronic pain”), and should there not be used except as a last-resort.

10. Defendants knew that, barring exceptional circumstances, opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer.

11. Defendants further knew—and had known for years—that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of known significant side effects and addiction.^{5,6}

12. Defendants also knew that controlled studies on the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

13. Indeed, the U.S. Food and Drug Administration (“FDA”) has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.⁷

⁵ See, *e.g.*, Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Current Status, 1 Progress in Pain Res. & Mgmt. 247 (1994).

⁶ The authoritative Diagnostic and Statistical Manual of Mental Disorders, (5th ed. 2013) (“DSM-V”) “substance use disorders” are a spectrum that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, “addiction” refers to this range of substance use disorders.

14. According to the Centers for Disease Control (“CDC”), from 1999 to 2014, the sales of prescription opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.⁸

15. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone; are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.⁹ Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user’s breathing, causing respiratory depression and death.

16. Defendants’ success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants’ scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a “substantial increase in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of

⁷ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

⁸ Centers for Disease Control and Prevention, *Prescribing Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>, (last accessed April 30, 2018).

⁹ Since passage of the Controlled Substances Act (“CSA”) in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

prescriptive use.”¹⁰ It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors’ prescriptions.

17. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

18. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official said, “Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we’re facing.”¹¹

19. According to the CDC, opioid overdoses killed more than 45,000 people in the 12 months that ended in September, 2017. It is already the deadliest drug epidemic in American history.¹² If trends continue, lost lives from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.

¹⁰ G. Caleb Alexander et al., Rethinking Opioid Prescribing to Protect Patient Safety and Public Health, 308(18) JAMA 1865 (2012).

¹¹ Matt Pearce & Tina Susman, Philip Seymour Hoffman’s death calls attention to rise in heroin use, L.A. Times, Feb. 3, 2014, <http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204> (accessed July 17, 2018).

¹² The Editorial Board, *An Opioid Crisis Foretold*, (Apr. 21, 2018), <https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html>.

20. Between the start of the century and the year 2014, opioid-related death rates increased by 200%. Fourteen percent of that increase occurred between 2013 and 2014.¹³

21. The opioid epidemic is killing scores of individuals each day, and having a similarly drastic impact on the total price tag for emergency room care provided by Independent Emergency Room Physicians. According to the CDC, the United States is currently seeing the highest overdose death rates ever recorded.¹⁴ As opioid related deaths increase, the life expectancy in the United States has decreased.¹⁵

22. On October 28, 2017, the opioid crisis was declared a public health emergency.¹⁶

23. According to addiction programs, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

¹³ Id.

¹⁴Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months, says CDC*, THE GUARDIAN (March 6, 2018), <https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc>

¹⁵National Center for Health Statistics, Life Expectancy, available at <https://www.cdc.gov/nchs/fastats/life-expectancy.htm>, (last accessed April 30, 2018); Centers for Disease Control and Prevention, U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioids, (March 18, 2018), <https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html>

¹⁶Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, The New York Times (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>

24. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.¹⁷ The rate of opioid related emergency department visits nearly doubled.¹⁸

25. Independent Emergency Room Physicians directly bear the brunt of the opioid crisis. They are the main place most addicts and/or those with addiction related medical needs and issues will first seek care or attempt to obtain more opioids for their addiction. This was reasonably foreseeable by Defendants as a result of their actions and consequence to the opioid prescription epidemic. Defendants relied on Independent Emergency Room Physicians to mitigate the health consequences of their illegal activities. Defendants knew that but for Independent Emergency Room Physicians providing some safety net the number of overdose deaths and other related health issues would have been far greater.

26. In a 2021 survey of emergency physicians and professionals involved with billing for emergency department care, the most common response on the amount collected from uninsured patients for emergency physician professional services in 1,265 ED-Years for the period 2006-2021 was \$21-\$25. According to a May 2003 American Medical Association (AMA) study, emergency physicians annually incur, on average, \$138,300 of EMTALA-related bad debt. Approximately 95.2% of emergency physicians provide some EMTALA mandated care in a typical week and more than one-third of emergency physicians provide more than 30 hours of

¹⁷Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), <https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse>, (last accessed on April 26, 2018).

¹⁸Audrey J. Weiss, et al, *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf>

EMTALA-related care each week and in many circumstances and, depending on the state in question, may not cover emergency physician costs for providing service.¹⁹

27. This suit takes aim at a primary cause of the opioid crisis: the actions of Defendants. In order to expand the market for opioids and realize blockbuster profits, Defendants, through the use of unfair and deceptive practices, created a sea of change in the medical and public perception that the use of opioids were not just safe and effective for acute and palliative care, but also safe for use for long periods to treat more common aches and pains, like lower back pain, arthritis, and headaches.

II. THE ROLE OF DEFENDANTS IN CAUSING AND PERPETUATING THE OPIOID CRISIS

28. The Manufacturing and Marketing Defendants' goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

29. Distributor Defendants and National Retail Pharmacies Defendants—saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities under the Controlled Substance Act, and flooded affected areas with opioids well knowing they were contributing to, but profiting from, widespread addiction and human misery.

¹⁹ American College of Emergency Physicians, The Impact of Unreimbursed Care on the Emergency Physician, <https://www.acep.org/administration/reimbursement/the-impact-of-unreimbursed-care-on-the-emergency-physician/>

30. Manufacturing and Marketing Defendants, through a sophisticated, highly deceptive and unfair marketing campaign that began in the late 1990s, which deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

31. To accomplish this, Defendants spent hundreds of millions of dollars:

- a. developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids long-term use to treat chronic pain;
- b. deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids;
- c. recruiting prescribing physicians as paid speakers as a means to secure those physicians' future “brand loyalty” and extend their reach to all physicians;
- d. funding, assisting, encouraging, and directing certain doctors, known as “key opinion leaders” (“KOLs”), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs (“CMEs”) that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and
- e. funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”) that developed educational materials and treatment guidelines that were

then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

32. These efforts, executed, developed, supported, and directed by Manufacturing and Marketing Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants and the third parties whom they recruited and supported, all profited handsomely through their dissemination of the deceptive information. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

33. Working individually, with, and through these Front Groups and KOLs, Manufacturing and Marketing Defendants pioneered a new and far broader market for their potent and highly addictive drugs—the chronic pain market. Defendants persuaded doctors, patients, and others that what they had long understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use—was untrue, and to the contrary, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs' labels, Defendants:

- a. overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use;

- b. trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death;

c. overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

d. mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There was, and is, no competent or reliable scientific evidence to support Defendants' marketing claims, and there was, and is, a wealth of competent and reliable scientific evidence that these claims are simply false; and ;

e. deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence.

34. Even Defendants' KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, Defendants continue to disseminate their misleading and unfair marketing claims to this day.

35. Defendants' efforts were wildly successful in expanding opioid abuse. The United States is now awash in opioids. In 2012, healthcare providers wrote 259 million prescriptions for opioid painkillers—enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.

36. Together, opioids generated \$8 billion in revenue for drug companies in 2012. Of that amount, \$3.1 billion went to Non-Defendant Purdue for its OxyContin sales. By 2015, sales of opioids grew further to approximately \$9.6 billion.²⁰

37. It was Defendants' false marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

38. Indeed, the National Institutes of Health (“NIH”) not only recognizes the opioid abuse problem, but also identifies Defendants' “aggressive marketing” as a major cause: “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies.*”²¹

39. There is a direct correlation between the sales of opioids and deaths, emergency room treatment and hospitalizations caused by opioids.²²

40. According to the U.S. Centers for Disease Control and Prevention (“CDC”), the nation has been swept up in an opioid-induced “public health epidemic.”²³ The statistics are startling. Adult hospitalizations due to opioid misuse or dependence doubled from 2000 to 2012.

²⁰ D. Crow, Drugmakers hooked on \$10bn opioid habit, Financial Times (August 10, 2016) available at <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95> (accessed July 17, 2018).

²¹ America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed July 12, 2018) (*emphasis added*).

²² The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annu. Rev. Public Health 2015, accessed at <http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957> (accessed July 12, 2018).

²³ CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), <http://www.cdc.gov/washington/testimony/2014/t20140429.htm> (accessed July 12, 2018).

From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.²⁴ According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. One Defendant's own 2010 internal data shows that it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the trend of opioid poisonings was increasing from 1999-2008. For every death, more than 30 individuals are treated in emergency rooms.

41. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in 2010,²⁵ and adolescents are abusing opioids in alarming numbers.

42. The average health care costs for opioid abusers were 8 times higher than those of non-abusers.²⁶

43. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on the County and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost \$10-\$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on

²⁴Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), <https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse>, (last accessed on April 26, 2018).

²⁵ CDC, Prescription Painkiller Overdoses in the US (Nov. 2011), <https://www.cdc.gov/vitalsigns/painkilleroverdoses/> (accessed July 12, 2018).

²⁶Alen G. White, PhD, et al., *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in *Journal of Managed Care Pharmacy*, Vol. 11, No. 6 July/August 2005, at 469.

prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

44. As a direct result of the opioid and eventual heroin epidemic more than 17,000 Americans died from prescription opioids in 2015 and the number continues to steadily grow.²⁷

45. Statistics from the CDC found that in 2015, opioids were responsible for over 33,000 deaths nationwide.²⁸

46. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct has caused and/or is continuing to cause a national, state, and local opioid epidemic.

47. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Cephalon's labels for Fentora and Actiq) may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

²⁷ <https://www.bloomberg.com/news/articles/2017-06-28/life-after-opioids-drugmakers-scramble-to-concoct-alternatives> (accessed July 12, 2018)

²⁸ Executive Order 2017-146 (2017). Available at http://www.flgov.com/wp-content/uploads/orders/2017/EO_17-146.pdf (accessed July 12, 2018). *See also*, Executive Orders 2017-177 and 2017-230 (2017).

48. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

49. As stated above, the National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause.²⁹ As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes" are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

50. The rising numbers of persons addicted to opioids have led to an increase in health care services that Plaintiffs and the putative class he seeks to represent must provide for no compensation or below-market rate compensation.

51. The impacts of Defendants' conduct foreseeably include America's Emergency Room Departments and facilities. Under EMTALA, Independent Emergency Room Physicians

²⁹ America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at <http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2018/americas-addiction-to-opioids-heroin-prescription-drug-abuse> (accessed July 12, 2018) (emphasis added).

are not only required to “provide medical screening examination for individuals” that visit the emergency department for any emergency medical condition, but also to provide treatment to stabilize the medical condition, or appropriately transfer the individual to another hospital. 42 U.S.C. §§ 1395dd (a) & (b). “In general any individual (whether or not eligible for benefits under this subchapter) comes to a hospital emergency room department and is treated by an Independent Emergency Room Physician and the Independent Emergency Room Physician determines that the individual has an emergency medical condition, they must provide either— (A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or (B) for transfer of the individual to another medical facility in accordance with subsection (c).” 42 U.S.C. §1395dd (b).

52. Specifically, Plaintiffs, and the putative class they seek to represent, must deal with the consequences of a major increase in issues such as drug abuse, diversion,³⁰ and crimes related to obtaining opioid medications. Plaintiffs, and the putative class they seek to represent, have been severely and negatively impacted due to the fraudulent misrepresentations and omissions by Defendants regarding the use and risk related to opioids. In fact, upon information and belief, Defendants have been and continue to be aware of the high levels of diversion of their product.

53. As a direct and foreseeable consequence of Defendants’ wrongful conduct, Plaintiffs, and the putative class they seek to represent, have been required to provide millions of dollars of services for no compensation or substantially reduced compensation at below market rates. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse and

³⁰ The CDC defines using or obtaining opioids illegally as “diversion.”

misuse, including, but not limited to, substantial loss of appropriate compensation for increased emergency and medical care services and lost productivity and opportunity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs and the class that the seeks to represent.

54. As a direct and foreseeable consequence of Defendants' wrongful conduct Plaintiffs and the putative class they seek to represent had to obtain training on appropriate use of opioids and recognition of abuse for licensure causing Plaintiffs and the putative class they seeks to represent incur monetary loss and also lost opportunity costs. Plaintiffs, and the class they seek to represent, were also damaged by being forced to consider patient satisfaction survey results or face negative employment consequences. These surveys asked patients how satisfied they were with treatment. If OUD patients were not given desired opioids, although physician felt they were drug seeking, at times they gave the physician a negative rating causing damage to the physician.

55. Opioid users have presented and continue to present themselves to Plaintiffs claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy their cravings. Plaintiffs has incurred and continues to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise dealing with "pill seekers" before their true status can be determined and they can be rejected as patients.

56. Plaintiff has incurred and continues to incur substantial unreimbursed charges for its treatment of patients with opioid conditions. These patients with opioid-related conditions presented for treatment to Plaintiffs as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiffs' monetary losses with respect to treatment of

these patients are foreseeable to Defendants and are the proximate result of Defendants' acts and omissions previously specified herein.

57. Plaintiffs has incurred and continues to incur substantial unreimbursed expenses as the result of the opioid crisis which directly affect Independent Emergency Room Physicians. Specifically, Plaintiffs has suffered significant increases in administrative costs due to the increased number of opioid patients seen by emergency rooms in the States in which Plaintiff Masiowski and Clark have worked, and throughout the United States. Additionally, Plaintiffs has suffered increased costs related to non-medical staff, such as medical scribes, as the result of the increased number of patients seen by emergency rooms and Independent Emergency Room Physicians as the result of the Opioid Crisis.

58. The Defendants have marketed and continue to market their opiate products directly to Plaintiffs, and thus Plaintiffs were and are direct customers and victims of the Defendants' false, deceptive and unfair marketing of opioids described hereafter.

59. In sum, Plaintiffs and the putative class that they seek to represent have experienced economic costs directly related to the opioid epidemic, including substantial loss of income for having to provide emergency room medical services for either no compensation or payment substantially below market rates.

JURISDICTION AND VENUE

60. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiffs' federal claims that they form part of the same case or controversy.

61. This Court independently has subject matter jurisdiction over Plaintiffs' state law claims under 28 U.S.C. § 1332(d)(2)(A), because the matter in controversy, the aggregated claims of the individual Class members, exceeds the sum of five million dollars, exclusive of interest and costs, and Plaintiffs are citizens of a state different from Defendants. Under 28 U.S.C. §1332(d)(5), there are more than 100 members of the proposed class.

62. This Court has jurisdiction over this action pursuant to the provisions of S.C. Code § 36-2-803 in that Defendants, individually or acting by and through their authorized agents, officers, representatives, servants and employees, operated, conducted, transacted business in South Carolina; committed a tortious act within the state; caused tortious injury in the state; producing, manufacturing and/or distributing goods with the reasonable expectation that those goods were to be used or consumed within the state, which were so used and consumed; by, among other things:

a. Manufacturing, selling and distributing highly addictive prescription opioid drugs in South Carolina while engaging in a pattern and practice of disseminating patently false and misleading information about the safety and efficacy of these opioid drugs;

b. Intentionally diminishing the associated health hazards of prescription opioid drugs and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of these drugs;

c. Consensually submitting to the jurisdiction of South Carolina when obtaining a manufacturer or distributor license; and/or

d. Owning and/or operating a distribution center in South Carolina that distributes the Defendant manufacturers' prescription opioid drugs to the citizens of South Carolina.

63. Defendants derived substantial revenue as the result of the opioids which were distributed to physicians, patients, and others and later consumed by persons then residing in the United States. Defendants' intentional and tortious conduct is continuing and presently existing, arose out of or is incidental to each Defendant's interstate, intrastate and international business ventures conducted in the United States, and proximately caused the Plaintiffs to sustain losses and damages in the State of South Carolina, Ohio, and Georgia. Accordingly, the Defendants have the requisite minimum contacts with South Carolina necessary to constitutionally permit this Court to exercise jurisdiction because:

a. The Defendants' contacts with South Carolina, Ohio, and Georgia including, but not limited to, their manufacture, sale, distribution and/or promotion of highly addictive prescription opioid drugs, are directly related to and gave rise to this Complaint;

b. Defendants' purposefully availed themselves of the privilege of conducting business in South Carolina, Ohio, and Georgia by selling, distributing and/or promoting the use of highly addictive prescription opioid drugs to doctors, hospitals, patients, health insurers and other individuals throughout the South Carolina, Ohio, and Georgia, including, but not limited to Charleston County, South Carolina; Dorchester County, South Carolina; Aiken County, South Carolina; Orangeburg County, South Carolina; Allendale County, South Carolina; Richland County, South Carolina; Berkley

County, South Carolina; Shelby County, Ohio; Burke County, Georgia, and Douglas County, Georgia; and,

c. Defendants' fraudulent and deceptive marketing campaign and intentional misconduct was such that the Defendants should have reasonably anticipated being hauled into court.

64. Venue is proper in this District under 28 U.S.C. § 1391(b)(2), because Plaintiff Masiowski domiciled in this judicial district, because a substantial part of the events and omissions giving rise to Plaintiff's claims occurred in this judicial district, and under 28 U.S.C. § 1391 (b)(1) and § (c)(2), because all the Defendants are subject to personal jurisdiction in this state and in this judicial district, such that Defendants are deemed to reside in this state and in this judicial district.

PARTIES

I. PLAINTIFFS

65. Plaintiff Michael Masiowski, M.D., is an independent emergency room physician who has independently practiced in Dorchester County, SC., Berkley County, SC., Charleston County, SC., Allendale County, SC., Richland County, SC., Aiken County, SC., Orangeburg County, SC., Shelby County, OH., Burke County, GA., and Douglas County, GA for the relevant timeframe herein.

66. Plaintiff Simon Clark, D.O., is an independent emergency room physician who has practiced in Jackson County, Missouri during the relevant timeframe herein.

67. Plaintiffs have sustained significant damages as the result of Defendants conduct. A non-exhaustive list of said damages include, but are not limited to:

- a. Reduced or no compensation for the treatment of individuals with opioid-use-disorder.
- b. Increased administrative expenses related to the treatment of individuals with opioid-use-disorder.
- c. Increased staffing costs, such as medical scribe costs, associated with the increased number of patients with opioid-use-disorder.

II. DEFENDANTS

*A. Manufacturer and Marketing Defendants*³¹

68. The Manufacturing and Marketing Defendants’ push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, “education” programs, and other means, Manufacturing and Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

69. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know

³¹Cephalon and Associated Companies, Janssen and Associated Companies, Non-Defendant Endo and Associated Companies, Non-Defendant Insys Therapeutics, Purdue, Non-Defendant Mallinckrodt Entities, Actavis and Associated Companies, Teva Pharmaceuticals, and Aphena Pharma Solutions.

should be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

70. From the day they made the pills to the day those pills were consumed in each community, these manufacturers had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Manufacturing and Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Manufacturing and Marketing Defendants caused their profits to soar as more and more people became dependent on opioids.

71. Opioid manufacturing and distributing companies systematically and repeatedly disregarded the health and safety of their customers and the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

72. The Manufacturing and Marketing Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo-addiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) promoted the falsehood that long term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the

effectiveness of a version of OxyContin that purportedly provided twelve hours of pain relief; and (8) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction.

73. The Manufacturing and Marketing Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Manufacturing and Marketing Defendants for their support of the Manufacturing and Marketing Defendants’ marketing messages.

74. The Manufacturing and Marketing Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”). The Manufacturing and Marketing Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly “neutral” guidance, such as treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer and Marketing Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

75. Each Manufacturer and Marketing Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant’s misrepresentations has been confirmed by the

U.S. Food and Drug Administration (“FDA”) and the CDC, including by CDC’s *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.³²

76. In an open letter to the nation’s physicians in August 2016, the then U.S. Surgeon General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors. . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”³³

77. The Manufacturing and Marketing Defendants are listed below. At all relevant times, the Manufacturing and Marketing Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturing and Marketing Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty prevent diversion and report suspicious orders.

78. Purdue manufactures, promotes, sells, and distributes opioids in the United States and South Carolina, including the following:

a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist³⁴ tablet first approved in 1995 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for

³²See Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last accessed April 12, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), <https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines>

³³Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, available at <http://turnthetidex.org/> (last accessed April 12, 2018).

³⁴ An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

which alternative treatment options are inadequate.” Prior to April 2014,³⁵ Oxy Contin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”

b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, MS Contin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”

c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the “management of pain in patients where an opioid analgesic is appropriate.”

d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the “relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief.”

e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the “management of pain

³⁵ The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens’ petition by doctors. The changes were intended to clarify the existing obligation to “make an individualized assessment of patient needs.” The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing “Monitor for signs of misuse, abuse, and addiction” to “[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death.” Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., Labeling Supplement and PMR [Post-Marketing Research] Required (Sept. 10, 2013), <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf> (accessed July 12, 2018).

severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Butrans was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”

f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to requiredaily,around-the-clock,long-termopioidtreatmentandforwhich alternative treatment options are inadequate.

g. TarginiqER (oxycodonehydrochlorideandnaloxonehydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

79. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

80. Purdue is included herein to assist with the illustration of the history of the opioid abuse and misuse problem and the common scheme all the Manufacturing and Marketing Defendants engaged in. The Manufacturing and Marketing Defendants engaged in actions that also substantially contributed to the Opioid epidemic.

81. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

82. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petach Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation which is a wholly owned subsidiary of Teva Ltd. In Pennsylvania. Teva USA acquired Cephalon in October of 2011.

83. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, in the United States and South Carolina:

84. Actiq(fentanylcitrate)isaScheduleIIopioidagonistlozenge(lollipop)first approved in 1998 and indicated for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”

85. Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

86. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay \$425 million.³⁶

87. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for

³⁶ Press Release, U.S. Dep't of Justice, Biopharmaceutical Company. Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008)<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed Jul. 12, 2018).

Cephalon in the United States through Teva USA and has done so since its October of 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

88. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.³⁷ Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 - the year immediately following the Cephalon acquisition- attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.³⁸ Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

89. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of

³⁷E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (accessed July 12, 2018).

³⁸ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf (accessed July 13, 2018)

JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July of 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen."

90. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales.

91. Until January 2015, Janssen developed, marketed, and sold the following opioids in the United States and South Carolina:

92. Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Nucynta ER was indicated for the "management of moderate to

severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.” The DPN indication was added in August 2012.

93. Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the “relief of moderate to severe acute pain in patients 18 years of age or older.”

94. Janssen (Noramco) sold the majority of its controlled substance through long term agreements and had such agreements with all 7 of the top U. S. generic drug companies.³⁹ It also grew to become the No. 1 narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the US. *Id.*

95. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

96. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTA VIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in

³⁹ State of Oklahoma v. Purdue, Case No. CJ-2017-816 Judge Balkman’s decision filed 8/26/10/19 para 14 findings of fact.

Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/ Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

97. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States, South Carolina and Missouri. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

98. APHENA PHARMA SOLUTIONS is a contract pharmaceutical manufacturing and packaging company that serves the pharmaceutical industry from two distinct operations in the United States — a solid-dose division in Tennessee and a liquid manufacturing and packaging campus in Maryland — both of which are both DEA licensed and FDA registered. Aphenia Pharma Solutions was originally formed by established contract pharmaceutical companies: PrePak, TestPak, Celeste, and Integrated Pharmaceutical Packaging. Their alliance is now called Aphenia Pharma Solutions. Aphenia Pharma Solutions maintained a Pharmaceutical/Distributor Market Share of 10.67% Charleston County S.C., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in Charleston County S.C. intermittently during this period.

*B. Distributor Defendants*⁴⁰

99. The Distributor Defendants are identified below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the United States.

100. McKESSON CORPORATION ("McKesson") is a Delaware corporation, with its principal place of business located in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina and Missouri.

a. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America

b. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion.

c. In its 2017 Annual Report, McKesson states that it "partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other

⁴⁰ McKesson Corporation, Cardinal, AmerisourceBergen Drug Corporation, Walmart Inc., Walgreens Boot Alliance/Walgreens Co., Smith Drug Company.

organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”⁴¹

d. According to the 2017 Annual Report, McKesson’s “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

e. McKesson Corporation (“McKesson”) is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country.

f. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice (“DOJ”) for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these “staged suspensions” as “among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor.”

101. McKesson is the largest pharmaceutical distributor in the United States

⁴¹McKesson, Annual Report, <http://investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017McKessonAnnualReport0.pdf> (last accessed April 12, 2018).

102. CARDINAL HEALTH, INC. ("Cardinal") is an Ohio corporation with its principal place of business located in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina and Missouri.

103. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over \$120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including S. Carolina, and has distributed opioids nationwide.

104. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina and Missouri.

105. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."⁴²

106. Collectively, McKesson, AmerisourceBergen, and Cardinal account for 85% of the drug shipments in the United States. These companies together collect about \$400 billion in annual revenue.

⁴²AmerisourceBergen, 2016 Summary Annual Report, <http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb> (last accessed April 12, 2018)

107. SMITH DRUG COMPANY is a full-line wholesale pharmacy distribution company serving independent community and long-term care pharmacies. It is based in Spartanburg, SC. Smith Drug Company utilizes electronic ordering and signing (CSOS) for ordering controlled substances. Their systems allow pharmacies to order and sign electronically, while complying with DEA guidelines. Smith Drug Company maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Allendale County S.C., Aiken County S.C., Orangeburg County, S.C., Douglas County S.C., Burke County S.C., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

108. WALGREENS BOOT ALLIANCE (WBA) is an American multinational holding company headquartered in Deerfield, Illinois, which owns the retail pharmacy chains Walgreens in the US and Boots in the UK, as well as several pharmaceutical manufacturing and distribution companies. Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including S. Carolina. Defendant Walgreens maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Berkley County, S.C., Orangeburg County S.C., Richland County S.C., Shelby County OH, Burke County GA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

109. The WALMART Pharmacy distribution network includes *a network of Walmart owned pharmacy distribution centers* located across the U.S. Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. (“Wal-Mart”), is a Delaware corporation with its principal place of business in Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription

opioids throughout the United States, including S. Carolina. Wal-Mart maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Dorchester County, S.C., Berkley County S.C., Aiken County S.C., Orangeburg County, S.C., Richland County S.C., Shelby County OH., Burke County GA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

C. National Retail Pharmacy Defendants

110. At all relevant times, the National Retail Pharmacy Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of a pharmacy to detect and warn of diversion of dangerous drugs for non-medical purposes. The National Retail Pharmacy Defendants universally failed to comply with federal law. Plaintiffs allege the unlawful conduct by the National Retail Pharmacy Defendants is responsible for the volume of prescription opioids plaguing the United States.

111. CVS HEALTH CORPORATION (“CVS”) is a Delaware corporation with its principal place of business in Rhode Island. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including S. Carolina. CVS maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Dorchester County, S.C., Berkley County S.C., Aiken County S.C., Orangeburg County, S.C., Richland County S.C., Shelby County SOH., Douglas County GA., Burke County GA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

112. THE KROGER CO. (“Kroger”) is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates more than 2,000 pharmacies in the United States, including in Ohio. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout

the United States, including in Shelby County, Ohio, a County where Plaintiff Masiowski practiced as an Independent Emergency Room Physician. From 2006 through 2019, Kroger maintained a 5.53% Market Share.

113. WALGREENS BOOT ALLIANCE (WBA) is an American multinational holding company headquartered in Deerfield, Illinois, which owns the retail pharmacy chains Walgreens in the US and Boots in the UK, as well as several pharmaceutical manufacturing and distribution companies. Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including S. Carolina. Defendant Walgreens maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Berkley County, S.C., Orangeburg County S.C., Richland County S.C., Shelby County OH., Burke County GA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

114. WALMART, INC., formerly known as Wal-Mart Stores, Inc. (“Wal-Mart”), is a Delaware corporation with its principal place of business in Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including S. Carolina. Wal-Mart maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Dorchester County, S.C., Berkley County S.C., Aiken County S.C., Orangeburg County, S.C., Richland County S.C., Shelby County OH., Burke County SGA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

D. PBM Defendants

115. The Express Scripts Defendants

a. **Defendant Evernorth Health, Inc.** (f/k/a Express Scripts Holding Company) (“Evernorth”) is a Delaware corporation Evernorth Health, Inc.’s principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

b. Evernorth is the parent company to all of the Express Scripts entities named as Defendants. Evernorth, through its executives and employees, controls the enterprise-wide policies that inform all of Express Scripts’ lines of business in order to maximize profits across the corporate family.

c. Evernorth’s conduct had a direct effect across communities in the United States, including Plaintiffs’ communities.

d. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts, Inc.’s principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

e. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout New York that engaged in the conduct which gives rise to this Complaint.

f. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail order services businesses, including with respect to the at-issue drugs, as well as Express Scripts’ data and research services.

g. **Defendant Express Scripts Administrators, LLC**, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Administrators, LLC’s principal place of business is at the same location as Express Scripts, Inc.

h. Express Scripts Administrators, LLC is registered to do business in New York and may be served through its registered agent CT Corporation System, 28 Liberty Street, New York, NY 10005.

i. During the relevant time period, Express Scripts Administrators, LLC provided and/or offered PBM services across communities in the United States, including Plaintiffs' communities., alleged in this complaint.

j. **Defendant Medco Health Solutions, Inc.** (f/k/a Merck-Medco) ("Medco") is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey, and is a wholly-owned subsidiary of Evernorth Health, Inc. Medco Health Solutions, Inc. was previously known as Merck-Medco. Merck-Medco was acquired in the early 1990s by Merck & Co. as its pharmacy benefit manager subsidiary. In 2002, Merck & Co. spun off Merck-Medco into a publicly traded company, defendant Medco Health Solutions, Inc.

k. Medco Health Solutions, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty Street, New York, NY 10005.

l. **Defendant ESI Mail Order Processing, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc.

m. During the relevant time period, ESI Mail Order Processing, Inc. provided and/or offered mail order pharmacy services across communities in the United States, including Plaintiffs' Communities, alleged in this Complaint, which gives rise to the causes of action herein.

n. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. ESI Mail Pharmacy Service, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

o. ESI Mail Pharmacy Service, Inc. d/b/a Express Scripts, Inc., does business in New York and may be served through Express Scripts' registered agent: CT Corporation System, 28 Liberty Street, New York, NY 10005.

p. During the relevant time period, ESI Mail Pharmacy Service provided mail order pharmacy services across communities in the United States, including Plaintiffs' Communities, as alleged in this Complaint, which gives rise to the causes of action herein.

q. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

r. Express Scripts Pharmacy, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty Street, New York, NY 10005.

s. Express Scripts Pharmacy, Inc. holds active licenses with the New York State Board of Pharmacy.

t. During the relevant time period, Express Scripts Pharmacy, Inc. provided and/or offered mail order pharmacy services across communities in the United States, including Plaintiffs' communities, alleged in this Complaint, which gives rise to the causes of action herein.

u. Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc. are referred to herein collectively as “Express Scripts Mail Order Pharmacy.”

v. In 2021, Express Scripts Mail Order Pharmacy was the third largest dispensing pharmacy in the United States and reported \$54.4 billion in prescription revenues.

w. From 2006 to 2014, Express Scripts Mail Order Pharmacy bought over 22.9 billion MMEs of opioids spread over 1.1 billion opioid dosage units.

x. **Defendant Express Scripts Specialty Distribution Services, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Specialty Distribution Services, Inc.’s principal place of business is at the same location as Express Scripts, Inc.

y. During the relevant time period, as alleged in more detail herein, Express Scripts Specialty Distribution Services, Inc. worked directly with the opioid manufacturers to expand the opioid market, including with Purdue to administer and dispense opioids through these opioid manufacturers’ Patient Assistance Programs, including in New York.

z. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Order Processing, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts Specialty Distribution Services, Inc., including all predecessor and successor entities, are referred to as “Express Scripts” or “ESI.”

aa. Express Scripts is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, and research provider; and (3) mail order pharmacy. During the

relevant time period, Express Scripts contracted directly with the opioid manufacturers in each of these capacities. At all relevant times, Express Scripts performed these services across communities in the United States, including Plaintiffs' Communities. In 2019, Express Scripts merged with Cigna, Inc. Prior to merging with Cigna, Express Scripts was the largest independent PBM in the United States.

bb. In 2012, Express Scripts acquired Medco in a \$29.1 billion deal.

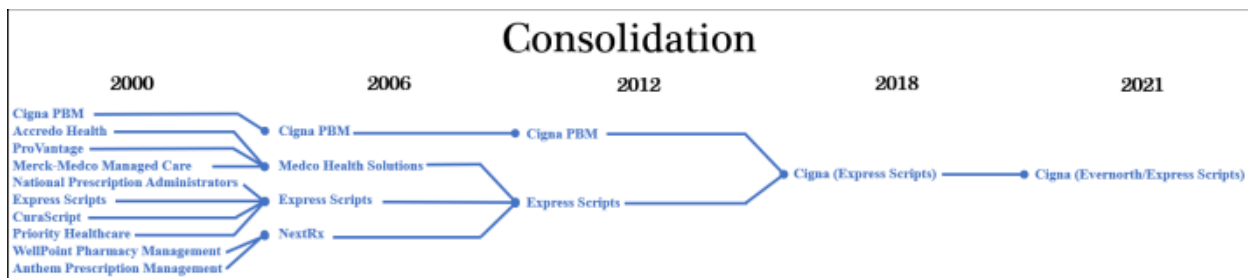
cc. Prior to 2012, Express Scripts and Medco were separate companies.

Standing alone, these companies were two of the largest PBMs in the country and had been since at least the mid-1990s.

dd. As a result of the merger, the combined Express Scripts was formed and became the largest PBM in the nation.

ee. Following the merger, all of Medco's PBM and data and research functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's clients becoming Express Scripts' clients and Medco's top executives becoming Express Scripts executives.

ff. The chart represents the consolidation of PBM entities that that are now all part of Express Scripts today:



gg. Express Scripts is now the largest PBM in the United States, with annual revenue (as of 2022) of over \$100 billion. Express Scripts provides pharmacy benefit service to more than 100 million Americans, filling 1.4 billion prescriptions per year.

hh. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard, national formularies that were offered to and used by Express Scripts' clients nationwide, including Plaintiffs' communities. Express Scripts' national formularies include its National Preferred Formulary, Basic Formulary, High Performance Formulary, and Prime Formulary. These Express Scripts formularies were utilized by prescription drug benefit plans in Plaintiffs' Communities throughout the relevant time period. At times relevant hereto, those formularies dictated the terms of reimbursement for opioids dispensed across communities in the United States, including Plaintiffs' Communities. Express Scripts offers pharmacy benefit services to a variety of plan sponsors with covered lives in the Plaintiffs' Communities, including both large national companies and local/regional businesses.

ii. Express Scripts (and/or its predecessors) processed claims for opioids dispensed pursuant to Express Scripts' national formularies and standard UM guidelines in Plaintiffs' Communities throughout the opioid epidemic.

116. The Optum Defendants

a. **Defendant UnitedHealth Group, Inc.** ("UnitedHealth Group" or "UHG") is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

b. UnitedHealth Group may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

c. UHG is registered to do business in New York and may be served through its registered agents: Griffin Michael, 914 3rd Avenue, Ste #126, Brooklyn, NY 11232 and Corporate Filings of New York, 90 State Street, Ste 700, Office 40, Albany, NY 12207.

d. UnitedHealth Group, Inc. is a Fortune 5 diversified managed healthcare company. In 2022, UnitedHealth Group listed revenue in excess of \$324 billion. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans and pharmacy benefits through its wholly-owned subsidiaries.

e. UnitedHealth Group operates through two connected divisions—Optum and UnitedHealthcare (“UHC”). As discussed in greater detail below, Optum provides PBM services; mail order pharmacy services; and data, analytics, consulting, and research services. UHC provides health insurance and health benefit services.

f. UnitedHealth Group, through its executives and employees, control the enterprise-wide policies that inform both UHC and Optum’s lines of business in order to maximize profits across the corporate family.

g. UnitedHealth Group’s conduct had a direct effect in New York, including Plaintiffs’ Communities.

h. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

i. Optum, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY 10005.

j. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth Group's pharmacy benefits, including OptumRx, Inc.

k. Since 2005, Optum, Inc. has been a part of the UnitedHealth Group. UnitedHealth Group has two major segments of its business: UnitedHealth Care ("UHC") which is its medical insurance arm and Defendant Optum, Inc., which includes UHG's PBM and research, data, and consulting arms. In 2022, UHC insured over 46 million Americans and generated \$249 billion in revenue.

l. Optum, Inc. is engaged in five types of business activities: (1) data analytics; (2) pharmacy benefit management; (3) healthcare services; (4) mail-order pharmacy dispensing; and (5) medical discount card services.

m. **Defendant OptumInsight, Inc.** (f/k/a Ingenix, Inc.) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OptumInsight was formerly known as Ingenix, Inc. The name change came after the State of New York investigated Ingenix related to a scheme to defraud consumers by manipulating reimbursement rates, resulting in a \$50 million settlement with the State and giving rise to U.S. Congressional hearings.

n. OptumInsight, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty Street, New York, NY 10005.

o. OptumInsight, Inc. holds an active Third-Party Administrator and Independent Adjuster license with the New York Department of Finance.

p. **Defendant OptumInsight Life Sciences, Inc.** (f/k/a QualityMetric, Inc.) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OptumInsight Life Sciences, Inc. is a wholly-owned subsidiary of UnitedHealth Group (“UHG”). Prior to 2011, OptumInsight Life Sciences, Inc. was known as QualityMetric.

q. OptumInsight, Inc., OptumInsight Life Sciences, Inc., as well as their predecessors, successors, affiliates, including but not limited to Innovus, Innovus Research, i3, QualityMetric, HTAnalysts, ChinaGate, and CanReg, are referred to herein as “OptumInsight.” OptumInsight is the Optum group that engages in data analytics.

r. OptumInsight emerged from a collection of entities acquired by the UnitedHealth Group over the years. Those legacy entities include Innovus, QualityMetric, HTAnalysts, ChinaGate, CanReg, Ingenix, and the Lewin Group.

s. As discussed more fully below, OptumInsight partnered with various opioid manufacturers to create studies, marketing, educational programs, and even identifying algorithms to simultaneously downplaying opioids’ addictive properties and expand its use and availability throughout the country, including in New York.

t. **Defendant OptumRx, Inc.** (“OptumRx”) is a California corporation with its principal place of business at 2300 Main St., Irvine, California, 92614. OptumRx is the arm of Optum that provides PBM and pharmacy dispensing services.

u. OptumRx is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY 10005.

v. OptumRx, Inc. entities (Optum Care Networks, Inc., Optum Services (Puerto Rico) LLC, OptumHealth Care Solutions Inc, OptumHealth Care Solutions LLC, and OptumInsight, Inc.) hold 4 active licenses with the New York State Department of Finance.

w. Prior to 2011, OptumRx was known as Prescription Solutions. In addition, as depicted in the PBM Consolidation Chart below, OptumRx grew as a result of numerous mergers and acquisitions. For example, in 2012, a large PBM, SXC Health Solutions, bought one of its largest rivals, Catalyst Health Solutions Inc. in a roughly \$4.14 billion deal. Shortly thereafter, SXC Health Solutions Corp. renamed the company Catamaran Corp. Following this, UHG bought Catamaran Corp. in a deal worth \$12.8 billion and merged Catamaran with OptumRx.

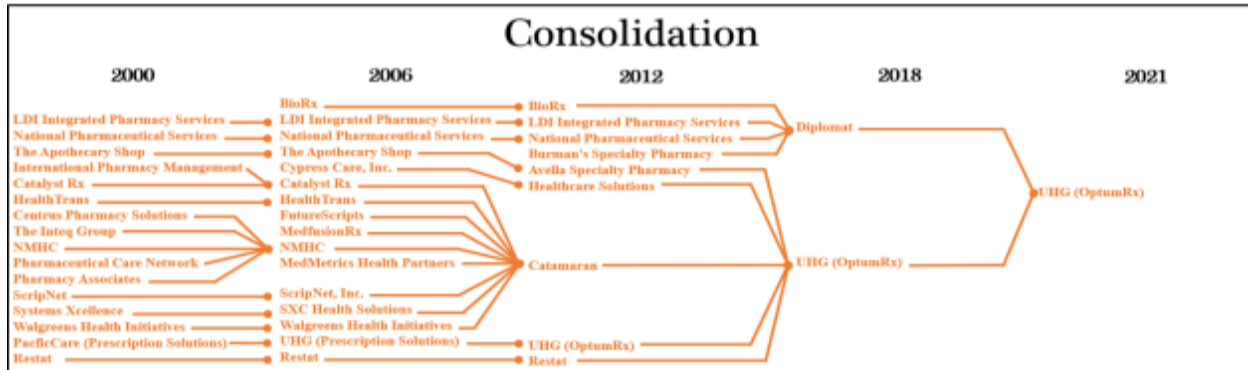
x. Prior to merging with OptumRx (or being renamed), Prescription Health Solutions, Catalyst Health Solutions, Inc., and Catamaran Corp. engaged in the at issue PBM and mail-order activities alleged more fully herein.

y. OptumRx now provides both PBM and mail-order dispensing services. At relevant times to this Complaint, OptumRx provided and/or offered PBM services for entities and/or persons in Plaintiffs' Communities.

z. At relevant times to this Complaint, OptumRx has sold and continues to sell prescription opioids through its mail order pharmacies in New York, including in Plaintiffs' Communities.

aa. OptumRx and all of its predecessors, including but not limited to Prescription Solutions, Catalyst Health Solutions, Inc., SXC Health Solutions Corp., and Catamaran Corp. are referred to herein as “OptumRx.”

bb. The consolidations that led to the emergence of OptumRx in its current form are shown on the chart below:



cc. **Defendant OptumRx Discount Card Services, LLC** is a Delaware limited liability company with its principal place of business at 1423 Red Ventures Drive Building RV4, 3rd Floor, Fort Mill, South Carolina 29707.

dd. OptumRx Discount Card Services, LLC is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY 10005 and at 111 eighth Avenue, New York, NY 10011.

ee. OptumRx Discount Card Services, LLC (f/k/a HealthTran, Inc., Catamaran PBM of Colorado, LLC, and Catamaran Discount Card Services, LLC) contracts with third-party businesses to administer prescription discount cards on their behalf. For example, the AARP’s prescription discount card program is “endorsed” by the AARP, but is otherwise run by Optum Discount Card Services, which pays the AARP a royalty fee to the AARP for use of its intellectual property.

ff. Defendant Optum Perks, LLC is a Delaware limited liability company with its principal place of business in Livonia, Michigan.

gg. Optum Perks offers a free pharmacy discount card in New York.

hh. Optum Perks, LLC (f/k/a Script Relief, LLC) is a discount card program that originally started as a joint venture between Loeb Enterprises, LLC, and Catalyst, where by 2012 Catalyst had a 47% ownership interest. Per Catamaran's 2012 10-K, "Script Relief is a variable interest entity with Catamaran being the primary beneficiary, as the Company's underlying PBM and pharmacy contracts represent Script Relief's key business operations and the Company has the power to direct these activities."

ii. By 2019, OptumRx, Inc. had fully acquired Script Relief and renamed the program Optum Perks.

jj. **Defendant OptumHealth Care Solutions, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344.

kk. OptumHealth Care Solutions, LLC is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY.

ll. Additionally, OptumHealth Care Solutions, LLC holds an active license with the New York State Department of Finance.

mm. OptumHealth for a number of years partnered with Purdue to educate many case managers, nurse practitioners, and medical directors throughout UnitedHealth Group's various enterprises. These programs were specifically endorsed and coordinated through one of Optum Health's national medical directors. The content of these programs

targeted pain as an undertreated disease, among other issues, and contained the similar dangerous messaging regarding the use of OxyContin that Purdue plead guilty to in 2007.

nn. **Defendant OptumHealthHoldings, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344.

oo. **Defendant OptumHealth Networks, Inc.** is a Delaware corporation with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota 55343.

pp. OptumHealth Networks, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY.

qq. OptumHealth Networks, Inc. provides care services to enrolled members of its subsidiaries and parents that includes care management services, arranging for delivery of services, and managing client relationships and contracts for access to said services.

rr. Together, OptumHealth Care Solutions, LLC, OptumHealth Holdings, LLC, and OptumHealth Networks, Inc. are referred to herein as “OptumHealth.”

ss. OptumHealth is a healthcare service provider that includes specialty health services, health banking services, ancillary care networks, and health education and information services to both individuals and health care professionals. It does this through four main lines of business: Care Solutions, Behavioral Solutions, Specialty Benefits, and Financial Services. In 2022, OptumHealth served 102 million individuals.

tt. Relevant to the opioid epidemic and Plaintiffs’ claims—detailed infra—OptumHealth partnered with Purdue throughout the 2000s to provide “education” to

health care providers, including medical directors, nurse practitioners, case managers, and care advisors throughout the country regarding the so-called “undertreatment” of pain and expanding the use of opioids.

uu. Collectively, OptumRx, Optum, Inc., Optum Discount Card Services, LLC, Optum Perks, LLC, OptumHealth Care Services, LLC, OptumHealth Holdings, LLC, OptumHealth Networks, Inc., and OptumInsight are referred to herein as “Optum.”

vv. Optum is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, consulting, and research provider; and (3) mail-order pharmacy. During the relevant time period, Optum contracted directly with opioid manufacturers in each of these capacities. At times relevant to this Complaint, Optum performed these services and derived substantial revenue across communities in the United States, including Plaintiffs’ Communities.

ww. Optum, Inc. is a health services company comprising three sectors—OptumRx, which manages pharmacy benefits for both UHC and third party clients; OptumHealth, which provides medical services as well as education and support for individuals throughout the country; and OptumInsight, which is the data, research, and consulting sector.

xx. OptumRx is the third largest PBM in the United States. It provides PBM services to more than 65 million people.

yy. OptumRx offered pharmacy benefit management services nationwide and maintained standard, national formularies that were offered to and used OptumRx’s clients both across the country and in Plaintiffs’ Communities. At all times relevant hereto, those formularies included opioids, including those at issue in this case. OptumRx

national formularies include the Essential Health Benefits, Generic Centric, Core Standard, Core Choice, Select Standard, Select Choice, Premium Standard, and Premium Choice.

zz. Optum (and/or its predecessors) processed claims for opioids dispensed pursuant to Optum's standard, national formularies and utilization management guidelines in Plaintiffs' Communities throughout the opioid epidemic.

aaa. In addition to its pharmacy benefit services, Optum entities also provide services related to pharmaceutical reimbursement and dispensing that generate revenue and benefit from a lack of opioid controls.

bbb. At times relevant hereto, Optum offered mail-order pharmacy services and dispensed opioids across communities in the United States, including Plaintiffs' Communities.

ccc. In 2021, Optum's mail order pharmacy was the fourth largest dispensing pharmacy in the United States and received \$34.2 billion in prescription revenues.

ddd. From 2006 to 2014, Optum's mail order pharmacy bought over 4.5 billion MMEs of opioids spread over 252 million opioid dosage units.

eee. OptumInsight, Optum's data, research, and consulting arm, is one of the largest health information, technology, and consulting companies in the world. It collects, processes, sells and profits from the vast data all managed lives—which in 2011 covered over 75 million lives. It also provides clinical research, consulting, marketing advisory services, and analytics tools to its clients.

fff. OptumInsight is an integral part of the conduct that gives rise to Plaintiffs' causes of action. As alleged in detail herein, throughout the relevant time period,

OptumInsight worked directly with opioid manufacturers to convince patients, prescribers, payors and the public that long term opioid use was appropriate for the treatment of chronic pain and that opioids were not addictive.

ggg. Each opioid manufacturer had dedicated executives assigned to work with OptumInsight. The opioid manufacturers used their relationships with OptumInsight to deepen their ties to the overall Optum corporate family.

hhh. OptumInsight was paid tens of millions of dollars by the opioid manufacturers during the relevant time period for its work to expand the opioid market.

iii. Plaintiffs adopts and incorporates into this complaint the allegations stated in paragraphs 203 through 506 in the document entitled "Plaintiff The City of Rochester, New York's Supplemental and Amended Allegations to be Added to the Verified Complaint and Jury Demand," Docket #5346-1, from case 1:17-md-02804-DAP.

E. Defendants' Agents

117. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

CONTINUING VIOLATIONS

118. This Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and

accumulating harm within the applicable statutes of limitations. Thus, Plaintiffs can recover for damages that it suffered during any applicable limitations period.

FACTUAL ALLEGATIONS

I. THE OPIOID EPIDEMIC

119. Since passage of the Controlled Substances Act (“CSA”) in 1970, 21 U.S.C. § 801, et seq., opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety.

120. Opioids generally have been categorized as Schedule II, although some are classified as Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

121. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as Independent Emergency Room Physicians, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

122. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.⁴³

123. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every four (4) hours for one (1) month.⁴⁴

124. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels.

The News Release noted:

1. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
2. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
3. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
4. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
5. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
6. Almost 5,500 people start to misuse prescription painkillers every day.⁴⁵

125. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.⁴⁶

⁴³See *Richard C. Dart et al.*, Trends in Opioid Analgesic Abuse and Mortality in the United States, 372 N.Eng. J. Med. 241 (2015).

⁴⁴ Katherine M. Keyes *et al.*, Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).

⁴⁵See Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

126. According to the CDC, opioids are responsible for the majority of drug overdoses today.⁴⁷ Additionally, opioid overdose have quadrupled nationally since 1999.⁴⁸

127. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.⁴⁹

128. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

129. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

130. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

131. Almost 5,500 people start to misuse prescription painkillers every day.⁵⁰

132. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed

⁴⁶William Wan & Mark Berman, *States to Try New Ways of Executing Prisoners. Their Latest Idea? Opioids.*, THE WASHINGTON POST (Dec. 9, 2017),https://www.washingtonpost.com/national/health-science/states-choose-new-ways-to-execute-prisoners-their-latest-idea-opioids/2017/12/09/3eb9bafa-d539-11e7-95bf-df7c19270879story.html?utm_term=.c7048831bfcd.

⁴⁷Centers for Disease Control and Prevention, *Heroin Overdose Data*,<https://www.cdc.gov/drugoverdose/data/heroin.html> (last accessed April 12, 2018).

⁴⁸ Id.

⁴⁹See Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771,<http://www.nejm.org/doi/full/10.1056/NEJMra1507771>, (hereinafter “Volkow and McLellan”).

⁵⁰ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html (accessed Jul. 12, 2018).

roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.⁵¹

133. Across the nation, emergency rooms are struggling with a wicked, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.⁵²

134. The National Institute on Drug Abuse identifies misuse and addiction to opioids as an epidemic.⁵³

135. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the “grave risks” of opioids, including “addiction, overdose, and even death.” The FDA further warned, “[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.” Because of those grave risks, the FDA said that long-acting extended-release opioids “should be used only when alternative treatments are inadequate.”⁵⁴ The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks on their labels.

136. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release for opioid pain

⁵¹ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016),

https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf (accessed Jul. 12, 2018)

⁵² Opioid Crisis, NIH, National Institute on Drug Abuse (available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, (accessed July. 12, 2018) (“Opioid Crisis, NIH”) (citing at note I Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid Involved Overdose Deaths - United States, 2010-2015, MMWR MORE MORTAL WKLY REP. 2016;65, doi:10.15585/mmwr.mm65051e1).

⁵³ See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”).

⁵⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physician for Responsible Opioid Prescribing, ReDocket No. FDA-2012-P-0818 (Sept. 10, 2013).

medications as it had for extended-release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.⁵⁵

137. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants for many years since they began marketing these drugs.

138. On March 29, 2017, then President Trump created The President's Commission on Combating Drug Addiction and the Opioid Crisis. On November 1, 2012 the Commission issued its final report and recommendations.

139. The President's Commission on Combating Drug Addiction and the Opioid Crises found "Contributors to the Current Crisis" in the U. S. to include, among other things:

- Use of the Porter & Jick letter to make unsubstantiated claims by pharmaceutical companies;
- The lack of high quality evidenced demonstrating that opioid can be used safely for chronic non-terminal pain;
- The use of the phrase "pain as the fifth vital sign, by the APS, JCAHO and others; and
- The fact that "[t]o this day, the opioid pharmaceutical industry influences the nation's response to the crisis.

140. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state, and local opioid epidemic.

II. THE MANUFACTURING AND MARKETING DEFENDANTS' MULTI-PRONGED SCHEME TO CHANGE PRESCRIBER HABITS, SWAY PUBLIC PERCEPTION, AND INCREASE DEMAND FOR OPIOIDS

141. In order to accomplish the fundamental shift in perception that was key to

⁵⁵ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm> (accessed July 12, 2018).

successfully marketing their opioids, the Manufacturing and Marketing Defendants designed and implemented a sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Manufacturing and Marketing Defendants turned to marketing techniques to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

142. The Manufacturing and Marketing Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing and Marketing Defendants of these risks. The Manufacturing and Marketing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use, and that patients were suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants’ misrepresentations.

143. The marketing scheme to increase opioid prescriptions centered around several categories of misrepresentations, which are discussed in detail below. The Manufacturing and Marketing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these Defendants funded and controlled, “Front Groups,” so-called industry “Key Opinion Leaders” (“KOLs”), and CME programs, all of which are discussed below.

A. The Manufacturing and Marketing Defendants Promoted Multiple Falsehoods About Opioids

144. The Manufacturing and Marketing Defendants made multiple misrepresentations about the risks and benefits of prescription opioids, including: (a) the risk of addiction from chronic opioid therapy is low; (b) to the extent there is a risk of addiction, it can be easily identified and managed; (c) signs of addictive behavior are “pseudo-addiction,” requiring more opioids; (d) opioid withdrawal can be avoided by tapering; (e) opioid doses can be increased without limit or greater risks; (f) long-term opioid use improves functioning; and (g) alternative forms of pain relief pose greater risks than opioids.

145. Each of these propositions was false. The Manufacturing and Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

146. While each Manufacturing and Marketing Defendant deceptively promoted its own opioid products specifically, and, together with other Manufacturing and Marketing Defendants, opioids generally, not every Manufacturing and Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Manufacturing and Marketing Defendant’s conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Manufacturing and Marketing Defendant’s misrepresentations and the manner in which they were disseminated, they are just that— examples.

1. MISREPRESENTATIONS ABOUT THE RISK OF ADDICTION

147. Central to the Manufacturing and Marketing Defendants’ promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Manufacturing and Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by “legitimate” pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Manufacturing and Marketing Defendants and substantially contributing to the opioid epidemic.

148. Each of the Manufacturing and Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

149. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, “even at recommended dose,”⁵⁶ and the risk substantially increases with more than three months of use.⁵⁷²⁵ As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).⁵⁸

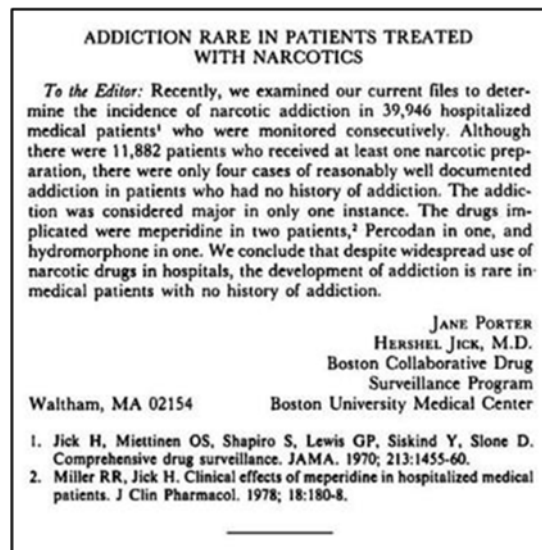
a. Purdue’s Misrepresentations Regarding Addiction Risk

⁵⁶*FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Extended- Release and Long-Acting Opioid Analgesics*, MagMutual (Aug. 18, 2016), <https://www.magmutual.com/learning/article/fda-announces-safety-labeling-changes-and-postmarket-study-requirements-opioids>; *see also* Press Release, U.S. Food & Drug Admin., FDA Announces Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death (Mar. 22, 2016), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm>.

⁵⁷ Deborah Dowell, M.D., *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, 65(1) *Morbidity & Mortality Wkly. Rep.* 1, 21 (Mar. 18, 2016) (hereinafter “CDC Guideline”).

⁵⁸*Id.* at 2.

150. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (“NEJM”) in 1980.



151. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.⁵⁹ The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in that patient’s records.

152. As Dr. Jick explained to a journalist years later, he submitted the statistics to

⁵⁹Jane Porter & Herschel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Engl. J. Med.* 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221> (hereinafter “Porter & Jick” or “Porter and Jick letter”).

NEJM as a letter because the data were not robust enough to be published as a study.

153. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper. Citation to the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Manufacturing and Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

154. Purdue specifically used the Porter and Jick letter in its 1998 promotional video, “I got my life back,” in which Dr. Alan Spanos says, “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.”⁶⁰ Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was 13%.⁶¹)

155. Other Manufacturing and Marketing Defendants relied on and disseminated the same distorted messaging. The enormous impact of Manufacturing and Marketing Defendants’ misleading amplification of this letter was well documented in another letter published in the *NEJM* on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

⁶⁰Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), <https://www.youtube.com/watch?v=Er78Dj5hyeI>.

⁶¹Patrick R. Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017) (hereinafter “Keefe, *Empire of Pain*”).

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.⁶²

156. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."⁶³

157. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared: "The fear of addiction is exaggerated."⁶⁴

158. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."⁶⁵

159. Purdue spun this baseless "legitimate use" distinction out even further in a

⁶²Pamela T.M. Leung, B.Sc. Pharm., *et al.*, *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Engl. J. Med. 2194 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150>.

⁶³Marilynn Marchione, Assoc. Press, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, STAT News (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter>.

⁶⁴Press Release, Purdue Pharma, L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996, 3:47pm), <http://documents.latimes.com/oxycontin-press-release-1996/>.

⁶⁵*OxyContin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Com.*, 107th Cong. 1 (Aug. 28, 2001) (Statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

patient brochure about OxyContin, called “A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.” In response to the question “Aren’t opioid pain medications like OxyContin Tablets ‘addicting’?” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

160. Sales representatives received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!” According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”

161. Purdue, through its website *Partners Against Pain*,⁶⁶ stated the following:

“Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.” “Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain.”

162. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing

⁶⁶*Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

OxyContin was that “it’s just too addictive.”⁶⁷ May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers that need to be taken every four hours.

163. According to interviews with prescribers and former Purdue sales representatives, Purdue continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

164. With regard to addiction, Purdue’s label for OxyContin has not sufficiently disclosed the true risks to, and experiences of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have “abuse potential” and that the “risk of abuse is increased in patients with a personal or family history of substance abuse.”

165. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient. Senior FDA officials met with Purdue on April 23, 2001, to “provide comments and suggestions on a Risk Management program for OxyContin.” Among other issues, the FDA noted that Purdue should add a black-box warning for overdose, abuse, and death to OxyContin’s label. Purdue acknowledged that it was aware of abuse of OxyContin orally (without tampering), as well as by snorting or injecting. It was not, the FDA explained, a matter of changing a few words in OxyContin’s label; Dr. Cynthia McCormick, then director of

⁶⁷Interview by Patrick Keefe with Steven Mays, former sales representative for Purdue Pharma, L.P., *How OxyContin Was Sold to the Masses*, The New Yorker (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

the FDA division overseeing pain medication, declared that “‘major overhaul is my message.’ The prescribing of OxyContin is creeping into a whole population of people where it doesn’t belong. Just rewriting the abuse and dependence section won’t help much, that part of the insert is not a pivot point.”

166. Another FDA participant asked that Purdue “refocus our promotional materials and make the risks of abuse and diversion more prominent.” In short, the FDA advised Purdue “that the information put in the label back at the time of product approval did not adequately address the risks associated with this product and this needs to be corrected.”

167. In 2001, Purdue revised the indication and warnings for OxyContin, but did not go nearly as far as the FDA recommended or the known risks of the product demanded. In the United States, Purdue ceased distributing the 160 mg tablet of OxyContin. While Purdue agreed to “consider” changes to its label, it also expressed a reluctance to make significant changes not required for other prescription opioids. Dr. McCormick noted that the issues discussed at the meeting were specific to OxyContin and that, while the agency would talk with Purdue’s competitors, “‘we have a problem here and now with OxyContin.’ In due time other manufacturers will be contacted but the first problem is this product.”

168. In the end, Purdue narrowed the recommended use of OxyContin to situations when “a continuous, around-the-clock analgesic is needed for an extended period of time” and added a warning that “[t]aking broken, chewed, or crushed OxyContin tablets” could lead to a “potentially fatal dose.” However, Purdue did not, until 2014, change the label as the FDA suggested, to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers but did not, as

the FDA suggested, issue “a Med guide for patients on the risks of overdose and the abuse of opioids as well as risks for use by others than those for whom it was prescribed” or undertake the recommended promotional effort to educate patients about the potentially fatal risks of OxyContin.

169. The FDA also informed Purdue what Purdue already knew, as noted above – that “there is a perception that oxycodone is safer than morphine.” A representative from the FDA’s Division of Drug Marketing, Advertising, and Communications echoed this, calling for an “extensive educational effort to consumers and health care practitioners” to “correct a misconception that [OxyContin] is different than morphine.” Upon information and belief, Purdue never undertook that effort.

b. Endo’s Misrepresentations Regarding Addiction Risk

170. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

171. Until April 2012, Endo’s website for Opana, www.Opana.com, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

172. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo’s training materials for its sales representatives in 2011 also prompted sales representatives to answer “true” to the statement that addiction to opioids is not common.

173. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below. Endo provided substantial assistance to, and exercised editorial control over, the deceptive and misleading messages that

APF conveyed through its National Initiative on Pain Control (“NIPC”)⁶⁸ and its website www.PainKnowledge.com, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

174. Another Endo website, www.PainAction.com, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

175. In a brochure available on www.PainKnowledge.com titled “*Pain: Opioid Facts*,” Endo-sponsored NIPC stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

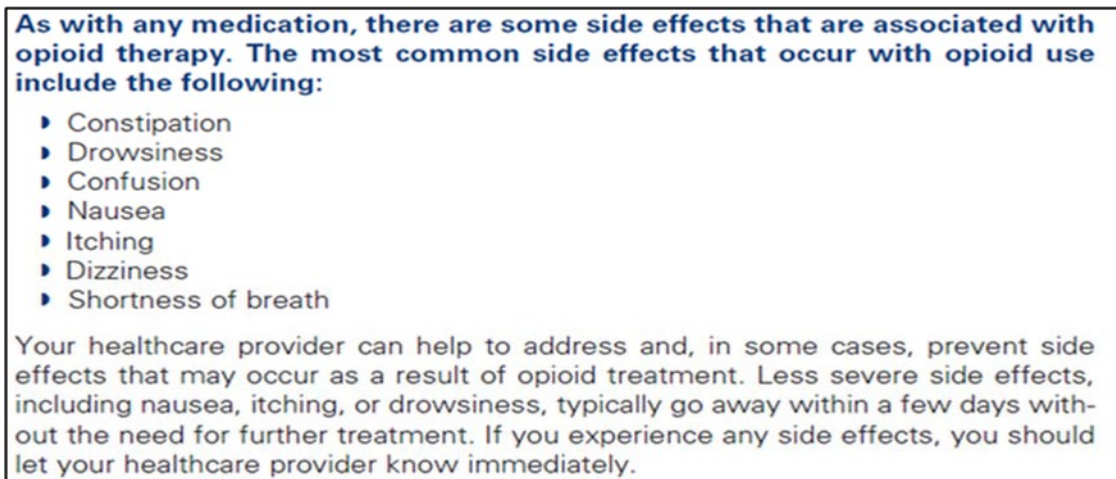
176. In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question – “What should I know about opioids and addiction?” – by focusing on explaining what addiction is (“a chronic brain disease”) and is not (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.” This publication is still available online.

177. An Endo publication, *Living with Someone with Chronic Pain*, stated, “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website, www.Opana.com, until

⁶⁸Endo was one of the APF’s biggest financial supporters, providing more than half of the \$10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

at least April 2012.

178. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *www.PainKnowledge.com*, omitted addiction from the “common risks” of opioids, as shown below:



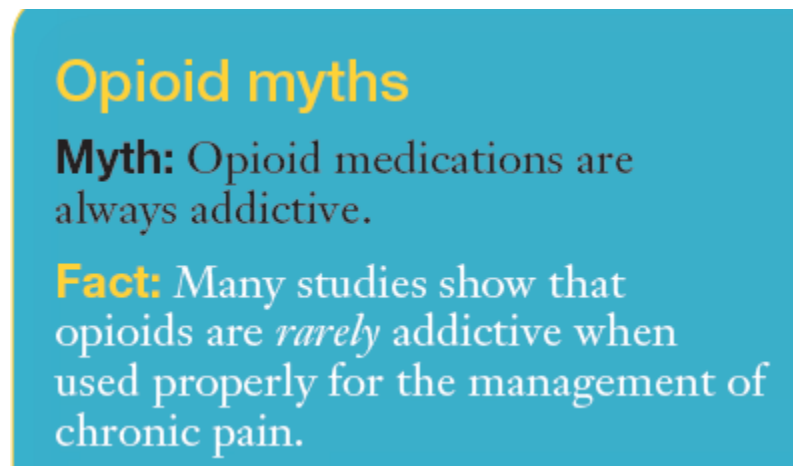
c. Janssen's Misrepresentations Regarding Addiction Risk

179. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding about addiction.” (Although Janssen described the website internally as an unbranded third-party program, it carried Janssen’s trademark and copy approved by Janssen.)

180. The *Let's Talk Pain* website also perpetuated the concept of pseudo-addiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain, which can be resolved with “effective pain management.” In August 2009, a “12-month review” of the *Let's Talk Pain* website manuscript confirmed that the website’s contents included statements regarding pseudo-addiction and illustrated Janssen’s control over the website and awareness of its contents.

181. A Janssen unbranded website, *www.PrescribeResponsibly.com*, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”⁶⁹

182. Janssen reviewed, edited, approved, and distributed a patient education guide entitled “*Finding Relief: Pain Management for Older Adults*,” which, as seen below, described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” Until recently, this guide was still available online.



183. Janssen’s website for Duragesic included a section addressing “Your Right to Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

184. According to an internal marketing assessment, Janssen sales representatives were trained to emphasize that Nucynta ER had fewer side effects than other opioids, though, upon information and belief, this was an untrue and unsubstantiated superiority claim.

⁶⁹Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Mgmt.*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last updated July 2, 2015).

185. Janssen also conducted a research study on prescribers regarding the visual aids for the marketing of Nucynta ER. Doctors reportedly were interested that Nucynta was described as appropriate for patients at risk for addiction and as a way to avoid addictive narcotics for young people. Additionally, doctors identified the advantages of Nucynta, which included that it was potentially less addicting than other opioids and had a lower street value.

186. Janssen also published a patient guide, *Patient Booklet Answers to Your Questions—Duragesic*, which stated that “[a]ddiction is relatively rare when patients take opioids appropriately.”

187. Janssen recognized that this misrepresentation was particularly important to payors, who had a “negative” reaction to covering an addictive drug for a chronic condition for which non-narcotic drugs were available.

d. Teva’s Misrepresentations Regarding Addiction Risk

188. Teva sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Teva sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

189. For example, a 2003 Teva-sponsored CME presentation titled “*Pharmacologic Management of Breakthrough or Incident Pain*,” posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population. The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact,

patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.⁷⁰

190. An internal “educational” document claimed that “in patients without personal or family history of substance abuse, addiction resulting from exposure to opioid therapy is uncommon.” The document continued, “Like patients, caregivers may need reassurance that few people using opioids for a legitimate medical reason become addicted to the drug, and that physical dependence to a drug is easily overcome through scheduled dosing decreases” Upon information and belief, this Teva “learning module” was used to train sales representatives for their interactions with prescribers.

e. Allergan’s Misrepresentations Regarding Addiction Risk

191. Through its “Learn More about customized pain control with Kadian” material, Allergan claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is “less likely” to happen in those who “have never had an addiction problem.” The piece goes on to advise that a need for a “dose adjustment” is the result of tolerance, and “not addiction.”

192. Training for Allergan sales representatives deceptively minimizes the risk of addiction by: (a) attributing addiction to “predisposing factors” like family history of addiction or psychiatric disorders; (b) repeatedly emphasizing the difference between substance dependence and substance abuse; and (c) using the term pseudo-addiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels

⁷⁰Michael J. Brennan, *et al.*, *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, <http://www.medscape.org/viewarticle/449803> (behind paywall).

doctors to respond to its signs with more opioids.

193. Allergan conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Allergan sales representatives' misstatements on the low-abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Allergan noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Allergan's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

194. A guide for prescribers under Allergan's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: (a) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users", and (b) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Allergan in 2007, before Allergan officially purchased Kadian from Alpharma. These statements convey both that:(a) Kadian does not cause euphoria and therefore is less addictive; and (b) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Allergan had no studies to suggest it was.

2. MISREPRESENTATIONS ABOUT MANAGING THE RISK OF ADDICTION

3. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Manufacturing and Marketing Defendants asserted that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

4. Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contained several screening tools and catalogues of Purdue materials that included these tools, with prescribers. Janssen, on its website www.PrescribeResponsibly.com, stated that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors.⁷¹ The website, which provided screening tools to prescribers for risk assessments, includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.⁷²

5. Purdue and Teva sponsored the APF’s *Treatment Options: A Guide for People*

⁷¹Howard A. Heit, M.D., FACP, FASAM & Douglas L. Gourlay, M.D., M.Sc., FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberresponsibly.com/articles/before-prescribing-opioids#pseudo-addiction> (hereinafter “Heit & Gourlay”) (last modified July 2, 2015).

⁷²*Risk Assessment Resources*, Prescribe Responsibly, <http://www.prescriberresponsibly.com/risk-assessment-resources> (last modified July 2, 2015).

Living with Pain (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed.”

6. Purdue sponsored a 2011 webinar taught by Dr. Lynn R. Webster, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

7. Purdue sponsored a 2011 CME program titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

8. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

9. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speakers’ bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (a) recommended screening patients using tools like the *Opioid Risk Tool* (“ORT”) created by Dr. Webster and linked to Janssen or the *Screening and Opioid Assessment for Patients with Pain*; and (b) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts. The ORT was linked to by Endo-supported websites, as well.

10. There are three fundamental flaws in the Manufacturing and Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

3. MISREPRESENTATIONS ABOUT "PSEUDO-ADDICTION"

11. The Manufacturing and Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudo-addiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."⁷³ In other words, people on prescription opioids who exhibited classic signs of addiction – for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids – were not addicted, but rather simply suffering from undertreatment of their pain.

12. In the materials and outreach they produced, sponsored, or controlled, the

⁷³David E. Weissman & J. David Haddox, *Opioid Pseudoaddiction – An Iatrogenic Syndrome*, 36(3) Pain 363 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565> ("Iatrogenic" describes a condition induced by medical treatment).

Manufacturing and Marketing Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

13. Teva, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007), written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudo-addiction."

14. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, www.PartnersAgainstPain.com, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudo-addiction" caused by untreated pain.

15. According to documents provided by a former Purdue sales representative, sales representatives were trained and tested on the meaning of pseudo-addiction, from which it can be inferred that sales representatives were directed to, and did, describe pseudo-addiction to prescribers. Purdue's Pain Management Kit is another example of publication used by Purdue's sales force that endorses pseudo-addiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." Upon information and belief, the kit was in use from roughly 2011 through at least June 2016.

16. Similarly, internal documents show that Endo trained its sales representatives to promote the concept of pseudo-addiction. A training module taught sales representatives that addiction and pseudo-addiction were commonly confused. The module went on to state, "The physician can differentiate addiction from pseudo-addiction by speaking to the patient about

his/her pain and increasing the patient's opioid dose to increase pain relief.”

17. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo-addiction and listed “[d]ifferentiation among states of physical dependence, tolerance, pseudo-addiction, and addiction” as an element to be considered in awarding grants to CME providers.

18. Endo itself later repudiated the concept of pseudo-addiction. In finding that “[t]he pseudo-addiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudo-addiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudo-addiction.’”⁷⁴ Endo thereafter agreed not to “use the term ‘pseudo-addiction’ in any training or marketing” in New York.

19. Janssen sponsored, funded, and edited a website called *Let’s Talk Pain*, which in 2009 stated “pseudo-addiction . . . refers to patient behaviors that may occur when ***pain is undertreated*** Pseudo-addiction is different from true addiction because such behavior can be resolved with effective pain management.” This website was accessible online until at least May 2012.

20. Janssen also currently runs a website, www.PrescribeResponsibly.com, which claims that concerns about opioid addiction are “overestimated,” and describes pseudo-addiction

⁷⁴Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 7.

as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases.”⁷⁵

21. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Webster, KOL discussed below, admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

4. MISREPRESENTATIONS ABOUT OPIOIDWITHDRAWAL

5. In an effort to underplay the risk and impact of addiction, the Manufacturing and Marketing Defendants also falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients’ dose to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids – adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for prolonged periods.

6. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient’s opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients

⁷⁵Heit & Gourlay, above.

who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

7. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

8. To this day, the Manufacturing and Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

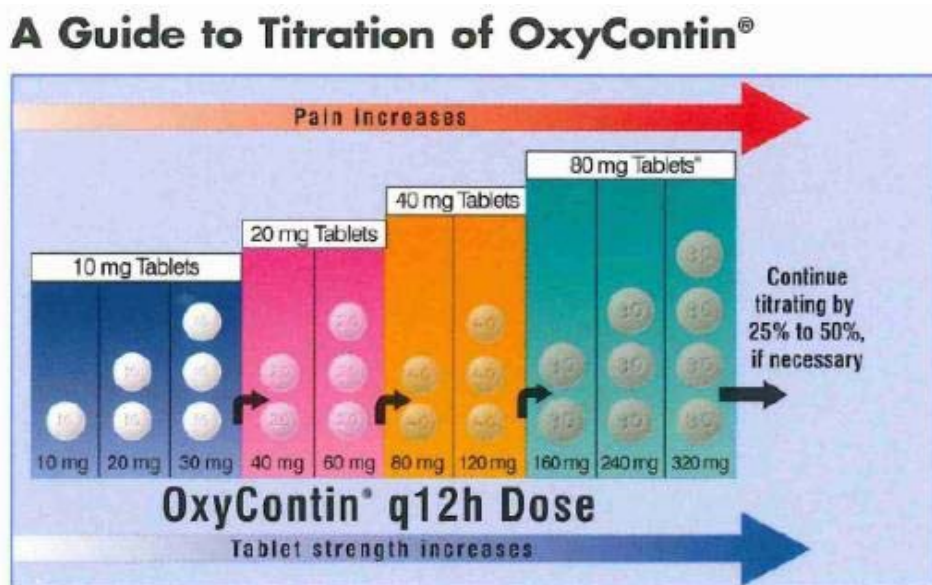
5. MISREPRESENTATIONS ABOUT OPIOID DOSING

6. In materials they produced, sponsored, or controlled, the Manufacturing and Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Manufacturing and Marketing Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

7. These misrepresentations were integral to the Manufacturing and Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so achieving long-term pain relief requires constantly increasing the dose.

8. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of

OxyContin.”⁷⁶ And the 2003 Conversion Guide for OxyContin contained the following diagram for increasing dose up to 320 mg:



9. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. “Doctor, what is the highest dose of OxyContin you have ever prescribed?” “20mg Q12h.” “Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?” “Okay.” “Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?” “I don’t know, maybe.” “Doctor, but you do agree that you would at least Rx the 40mg dose, right?” “Yes.”

The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

10. These misrepresentations were particularly dangerous. As noted above, opioid

⁷⁶Letter from Windell Fisher, Purdue Regional Manager, to B. Gergely, Purdue Employee (Nov. 7, 1996), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996> (hereinafter “Letter from Fisher”).

doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every 12 hours is ten times that.

11. In its 2010 Risk Evaluation and Mitigation Strategy (“REMS”) for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing the dose, and instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”⁷⁷

12. Endo sponsored a website, *www.PainKnowledge.com*, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

13. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased . . . You won’t ‘run out’ of pain relief.”

14. Purdue and Teva sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have “no ceiling dose” and therefore are safer than non-steroidal anti-inflammatory drugs (“NSAIDs”).

15. According to internal documents, Janssen sales representatives were trained to

⁷⁷Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, <https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

explain to physicians that patients' pain was reduced at higher doses and that they were undertreating pain by prescribing lower doses. For example, a 2012 *Nucynta ER Messaging Evolution Full Report* instructs sales representatives to overcome primary care providers' objections to high doses.

16. Higher dose prescribing was particularly important to Janssen because it knew that doctors did not believe that Nucynta ER provided adequate or equivalent pain relief. A few of the doctors who participated in the study voiced concerns over prescribing higher doses. In response, sales representatives were trained to address concerns by emphasizing approved dosing ranges.

17. Manufacturing and Marketing Defendants were aware of the greater dangers high-dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

6. MISREPRESENTATIONS ABOUT LONG-TERM OPIOID USE AND IMPROVED FUNCTIONING

18. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Manufacturing and Marketing Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

19. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork,

uninterrupted,” “[l]ife, uninterrupted,” “[g]ame, uninterrupted,” “[c]hronic pain relief that supports functionality,” and “[i]mprove[s] . . . physical and social functioning.”

20. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine . . . We do not have such data to support OxyContin promotion. In addition, Janssen has been using the “life uninterrupted” message in promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any quality of life claims.⁷⁸

21. Despite its acknowledgment that “[w]e do not have such data to support OxyContin promotion,” Purdue ran a full-page ad for OxyContin in the *Journal of the American Medical Association*, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users’ function. This ad earned a warning letter from the FDA, which admonished, “It is particularly disturbing that your November ad would tout ‘Life with Relief’ yet fail to warn that patients can die from taking OxyContin.”⁷⁹

22. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

⁷⁸Meier, *supra* note 9, at 281.

⁷⁹Chris Adams, *FDA Orders Purdue Pharma to Pull Its OxyContin Ads*, Wall St. J. (Jan. 23, 2003, 12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

23. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes” – case studies featuring patients with pain conditions persisting over several months – that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

24. Similarly, since at least May 2011, Endo has distributed and made available on its website, *www.Opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

25. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

26. In addition, Janssen’s *Let’s Talk Pain*, website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

27. The APF’s *Treatment Options: A Guide for People Living with Pain* (2007), sponsored by Purdue and Teva, counseled patients that opioids “give [pain patients] a quality of

life we deserve.” The guide was available online until APF shut its doors in May 2012.

28. Endo’s NIPC website, www.PainKnowledge.com, claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement.

29. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

30. The Manufacturing and Marketing Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life.⁸⁰ Based upon a review of the

⁸⁰The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. See Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (Mar. 24, 2008) (finding the claim that “patients, who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience”). The FDA’s warning letters were available to the Manufacturing and Marketing Defendants on the FDA website.

scientific evidence, the CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use.”

31. Consistent with the CDC’s findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had “consistently poor results,” and “several studies have showed that [using] opioids for chronic pain may actually worsen pain and functioning,” along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

32. The available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.” According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”

33. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and

these patients are unable to function normally.”⁸¹ In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.⁸² Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.⁸³

7. MISREPRESENTATIONS ABOUT ALTERNATIVE FORMS OF PAINRELIEF

34. In materials they produced, sponsored, or controlled, the Manufacturing and Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

35. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Manufacturing and Marketing Defendants routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over

⁸¹Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), <http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

⁸²Jeffrey Dersh, *et al.*, *Prescription Opioid Dependence is Associated With Poorer Outcomes in Disabling Spinal Disorders*, 33(20) *Spine* 2219 (Sept. 15, 2008).

⁸³Gary M. Franklin, *et al.*, *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: The Disability Risk Identification Study Cohort*, 33(2) *Spine* 199, 201-02 (Jan. 15, 2008).

time;”⁸⁴ hormonal dysfunction;⁸⁵ decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;⁸⁶ neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.⁸⁷

36. The APF’s *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Teva, warned that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.

37. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), which listed dose limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are “upset stomach or sleepiness,” which the brochure claims will go away, and constipation.

⁸⁴Letter from Janet Woodcock, M.D., Dir. of Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. of Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

⁸⁵Harry W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids*, 3(5) J. Pain 377(2001).

⁸⁶Bernhard M. Kuschel, *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People – A Swedish Case-Control Study*, 25(3) Eur. J. Pub. H. 527 (July 31, 2014).

⁸⁷Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. of Am. Med. Assoc. 940 (2012).

38. Endo's NIPC website, *Painknowledge.com*, contained a flyer called "*Pain: Opioid Therapy*." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

39. As another example, the Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

40. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."⁸⁸ The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose– and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.

41. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal

⁸⁸Charles E. Argoff, M.D., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News (Apr. 2007), http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf.

bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

42. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

43. As a result of the Manufacturing and Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.

B. The Manufacturing and Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

44. The Manufacturing and Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Manufacturing and Marketing Defendants; (2) so-called KOLs, that is, doctors who were paid by the Manufacturing and Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Manufacturing and Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers"; (8) speakers bureaus and programs; (9) the Pharmacy Defendants, who both received and disseminated the marketing messages; and (10)

the Major PBMs⁸⁹ who participated with the other Manufacturing and Marketing Defendants in disseminating the false and misleading information.

1. THE MANUFACTURING AND MARKETING DEFENDANTS
DIRECTED FRONT GROUPS TO DECEPTIVELY PROMOTE
OPIOID USE

45. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Manufacturing and Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These “Front Groups” put out patient education materials, treatment guidelines, and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.⁹⁰ Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages – often at the expense of their own constituencies.

46. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”⁹¹ “Even small organizations – with ‘their large numbers and credibility with policymakers and the public’ – have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach

⁸⁹The Major PBMs consist of CVS/Caremark, OptumRx, and Express Scripts.

⁹⁰*Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member’s Office at 3 (Feb. 12, 2018), <https://www.hsdl.org/?abstract&did=808171> (hereinafter, “*Fueling an Epidemic*”).

⁹¹*Id.* at 2.

capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”⁹² Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,⁹³ which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy,”⁹⁴ found that the Manufacturing and Marketing Defendants made millions of dollars of contributions to various Front Groups.

47. The Manufacturing and Marketing Defendants also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.⁹⁵

48. As the Senate *Fueling an Epidemic* Report found, the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”⁹⁶ They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC Guideline on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.”⁹⁷

49. The Manufacturing and Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front

⁹²*Id.*

⁹³*Id.* at 3.

⁹⁴*Id.* at 3.

⁹⁵*Id.* at 10.

⁹⁶*Id.* at 12-15.

⁹⁷*Id.* at 12.

Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with and through the Front groups, and with each other, to deceptively promote the use of opioids for the treatment of chronic pain.

a. American Pain Foundation

50. The most prominent of the Front Groups was the American Pain Foundation (“APF”). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Manufacturing and Marketing Defendants Purdue, Endo, Janssen, and Teva. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Purdue, Teva, Endo, and others to avoid using its line of credit. Endo was APF’s largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

51. For example, APF published a guide sponsored by Teva and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use, which are discussed below.

52. APF also developed the NIPC, which ran a facially unaffiliated website, *www.PainKnowledge.com*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including

a series of “dinner dialogues.” But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo’s control of NIPC was such that Endo listed it as one of its “professional education initiative[s]” in a plan Endo submitted to the FDA. Yet, Endo’s involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.PainKnowledge.com*. Endo estimated it would reach 60,000 prescribers through NIPC.

53. APF was often called upon to provide “patient representatives” for the Manufacturing and Marketing Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” (“PAP”) and Janssen’s “Let’s Talk Pain.” Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Manufacturing and Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that share [its] business interests.

54. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

55. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in

connection with that project. The agreement gave Purdue – but not APF – the right to end the project (and, thus, APF’s funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF’s lack of independence and willingness to harness itself to Purdue’s control and commercial interests, which would have carried across all of APF’s work.

56. APF’s Board of Directors was largely comprised of doctors who were on the Manufacturing and Marketing Defendants’ payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Manufacturing and Marketing Defendants demonstrates APF’s clear lack of independence, in its finances, management, and mission, and its willingness to allow Manufacturing and Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications – even when Defendants’ messages contradicted APF’s internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF’s formal summary of the meeting notes concluded that: “[An] important barrier [] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence.”

57. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective immediately.” Without support from Manufacturing and Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

b. American Academy of Pain Medicine and the American Pain Society

58. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from the Manufacturing and Marketing Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁹⁸ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

59. AAPM’s corporate council includes Purdue, Depomed, Teva, and other pharmaceutical companies.

60. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

61. AAPM describes the annual event as an “exclusive venue” for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants

⁹⁸*The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (as viewed Aug. 18, 2017).

Endo, Purdue, and Teva were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

62. AAPM’s staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

63. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Teva, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

64. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned

65. from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

66. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College’s Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as “skewed” by drug companies and “biased in many important respects,” including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

67. The 2009 Guidelines were a particularly effective channel of deception. They influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Manufacturing and Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can “change prescribing practices.”

68. The Manufacturing and Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines, or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009, titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain*, relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

c. Federation of State Medical Boards

69. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise FSMB have the power to license doctors, investigate complaints, and discipline physicians.

70. FSMB finances opioid- and pain-specific programs through grants from the Manufacturing and Marketing Defendants.

71. Since 1998, FSMB has been developing treatment guidelines for the use of

opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

72. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide.

73. FSMB’s 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo, and Teva. The publication also received support from the APF and the AAPM. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as “the leading continuing medical education (CME) activity for prescribers of opioid medications.” This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins, that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

74. The Manufacturing and Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of

discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

d. The Alliance for Patient Access

75. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styled itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.”⁹⁹ It is (or at least used to be) run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.¹⁰⁰ As of June 2017, APA listed 30 “Associate Members and Financial Supporters.” The list included J&J, Endo, Mallinckrodt, Purdue, and Teva.

76. Some of APA’s former board members also directly received substantial funding from pharmaceutical companies.¹⁰¹ For instance, former board vice president Dr. Srinivas Nalamachu, from Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from Endo, Purdue, and Teva. Dr. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys Therapeutics, Inc. and its payment of kickbacks to physicians who prescribed Subsys. Other former board members included Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015

⁹⁹*About AfPA*, The Alliance for Patient Access, <http://allianceforpatientaccess.org/about-afpa> (last visited June 14, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

¹⁰⁰Mary Chris Jaklevic, *Non-Profit Alliance for Patient Access Uses Journalists and Politicians to Push Big Pharma’s Agenda*, Health News Rev. (Oct. 2, 2017), <https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda>.

¹⁰¹All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica’s Dollars for Docs database, <https://projects.propublica.org/docdollars>.

from pharmaceutical companies, including payments by Teva and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Mallinckrodt and Teva; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Purdue, Mallinckrodt, and Teva; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

77. Among its activities, APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.”¹⁰² Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

* * *

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.

78. The white paper also purports to express concern about policies that have been

¹⁰²Pain Therapy Access Physicians Working Group, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse* (Dec. 2013), http://1yh21u3cjpvtv3xjderldco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board-certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. [I]t is not even certain that the regulations are helping prevent abuses.

79. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. Physicians can face similar stigma from peers.

Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.

80. In conclusion, the white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”

81. APA also issued “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported APA’s agenda.

82. APA also lobbies Congress directly. In 2015, APA signed onto a letter

supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill “could actually result in increased diversion, abuse, and public health and safety consequences”¹⁰³ and, according to DEA chief administrative law judge John J. Mulrooney (“Mulrooney”), the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like the Defendants here, in the federal courts.¹⁰⁴ The bill passed both houses of Congress and was signed into law in 2016.

e. The U.S. Pain Foundation

83. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Manufacturing and Marketing Defendants. The USPF was one of the largest recipients of contributions from the Manufacturing and Marketing Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Manufacturing and Marketing Defendants’ lobbying efforts to reduce the limits on over-prescription. The USPF advertised its ties to the Manufacturing and Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (*i.e.*, Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members. Industry Front Groups like the American Academy of Pain Management, the AAPM, the APS, and Pharmaceutical Research and Manufacturers of America

¹⁰³Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress>.

¹⁰⁴John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. 333, 346 (2017).

(“PhRMA”) were also members at varying levels in the USPF.

f. American Geriatrics Society

84. The American Geriatrics Society (“AGS”) was another Front Group with systematic connections and interpersonal relationships with the Manufacturing and Marketing Defendants. AGS was a large recipient of contributions from the Manufacturing and Marketing Defendants, including Endo, Purdue, and Janssen. AGS contracted with Purdue, Endo, and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons* (“2002 AGS Guidelines”) and 2009 (Pharmacological Management of Persistent Pain in Older Persons (“2009 AGS Guidelines”)). According to news reports, AGS received at least \$344,000 in funding from opioid manufacturers since 2009. AGS’s complicity in the common purpose with the Manufacturing and Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

85. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied

on by researchers and prescribers) since their 2009 publication and as recently as this year.

86. Representatives of the Manufacturing and Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts, and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

87. Members of AGS Board of Directors were doctors who were on the Manufacturing and Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

2. THE MANUFACTURING AND MARKETING DEFENDANTS PAID KEY OPINION LEADERS TO DECEPTIVELY PROMOTE OPIOID USE

88. To falsely promote their opioids, the Manufacturing and Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Manufacturing and Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Manufacturing and Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and legitimate medical professionals favored the wider and broader use of opioids.

89. Although these KOLs were funded by the Manufacturing and Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

90. As the Manufacturing and Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

91. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

92. In return for their pro-opioid advocacy, the Manufacturing and Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster received funding from Endo, Purdue, and Teva. Dr. Fine received funding from Janssen, Teva, Endo, and Purdue.

93. The Manufacturing and Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Manufacturing and Marketing Defendants' agenda. The Manufacturing and Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Manufacturing and Marketing Defendants kept these KOLs well-funded to enable them to push the Manufacturing and Marketing Defendants' deceptive message out to the medical community.

94. Once the Manufacturing and Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Manufacturing and Marketing Defendants' false position that opioids were safe and effective for treatment of

chronic pain, the Manufacturing and Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Manufacturing and Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Manufacturing and Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

95. In their promotion of the use of opioids to treat chronic pain, the Manufacturing and Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Manufacturing and Marketing Defendants.

3. THE MANUFACTURING AND MARKETING DEFENDANTS DISSEMINATED THEIR MISREPRESENTATIONS THROUGH CONTINUING MEDICAL EDUCATION PROGRAMS

96. Now that the Manufacturing and Marketing Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

97. One way the Manufacturing and Marketing Defendants aggressively distributed their false message was through thousands of continuing medical education (CME) courses.

98. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs

not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

99. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Manufacturing and Marketing Defendants' deceptions.

100. The Manufacturing and Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

101. Teva sponsored numerous CME programs, which were made widely available through organizations like Medscape, and which disseminated false and misleading information to physicians across the country.

102. Another Teva-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who treated "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a

non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway.”¹⁰⁵ The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

103. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

104. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman.

105. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

106. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs create, stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urges that “[w]hen possible,

¹⁰⁵Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale with Opioids*, Medscape (Sept. 16, 2003), <http://www.medscape.org/viewarticle/461612>.

CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”¹⁰⁶

107. Physicians attended or reviewed CMEs sponsored by the Manufacturing and Marketing Defendants during the relevant time period and were misled by them.

108. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Manufacturing and Marketing Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Manufacturing and Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Manufacturing and Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers’ views on opioids. Producers of CMEs and the Manufacturing and Marketing Defendants both measured the effects of CMEs on prescribers’ views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

4. THE MANUFACTURING AND MARKETING DEFENDANTS USED “BRANDED” ADVERTISING TO PROMOTE THEIR PRODUCTS TO DOCTORS AND CONSUMERS

109. The Manufacturing and Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Manufacturing and Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical*

¹⁰⁶Opinion 9.0115, Financial Relationships with Industry in Continuing Medical Education, Am. Med. Ass’n (Nov. 2011), at 1.

Association. The Manufacturing and Marketing Defendants collectively spent more than \$14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

110. The Manufacturing and Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.¹⁰⁷ They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.¹⁰⁸ Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Manufacturing and Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

5. THE MANUFACTURING AND MARKETING DEFENDANTS USED "UNBRANDED" ADVERTISING TO PROMOTE OPIOID USE FOR CHRONIC PAIN WITHOUT FDA REVIEW

111. The Manufacturing and Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness" – encouraging consumers to "talk to your doctor" about a

¹⁰⁷In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. John B. McKinlay, Ph.D., *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(4) Med. Care 294 (Apr. 2014).

¹⁰⁸*Id.*

certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (*i.e.*, the condition which the drug is approved to treat) must also include possible side effects and contraindications – what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Manufacturing and Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

112. Many of the Manufacturing and Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.InTheFaceOfPain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

6. THE MANUFACTURING AND MARKETING DEFENDANTS FUNDED, EDITED, AND DISTRIBUTED PUBLICATIONS THAT SUPPORTED THEIR MISREPRESENTATIONS

113. The Manufacturing and Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and

was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

114. To accomplish their goal, the Manufacturing and Marketing Defendants – sometimes through third- party consultants and/or Front Groups – commissioned, edited, and arranged for the placement of favorable articles in academic journals.

115. The Manufacturing and Marketing Defendants’ plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Manufacturing and Marketing Defendants’ marketing departments.

116. The Manufacturing and Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Manufacturing and Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter and Jick letter. The Manufacturing and Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

117. The Manufacturing and Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

118. For example, in 2007 Teva sponsored the publication of an article titled “Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain Patient

Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,”¹⁰⁹ published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article’s authors (including Dr. Webster, discussed above) stated that the “OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Dr. Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP- specific therapy suggests several domains that may be helpful in developing BTP- specific, QoL assessment tools.¹¹⁰

7. THE MANUFACTURING AND MARKETING DEFENDANTS USED DETAILING TO DIRECTLY DISSEMINATE THEIR MISREPRESENTATIONS TO PRESCRIBERS

119. The Manufacturing and Marketing Defendants’ sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Manufacturing and Marketing Defendants’ sales representatives also distributed third-party marketing material to their target audience that was deceptive.

120. Each Manufacturing and Marketing Defendant promoted opioids through sales

¹⁰⁹Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) *Pain Med.* 281-88 (Mar. 2007).

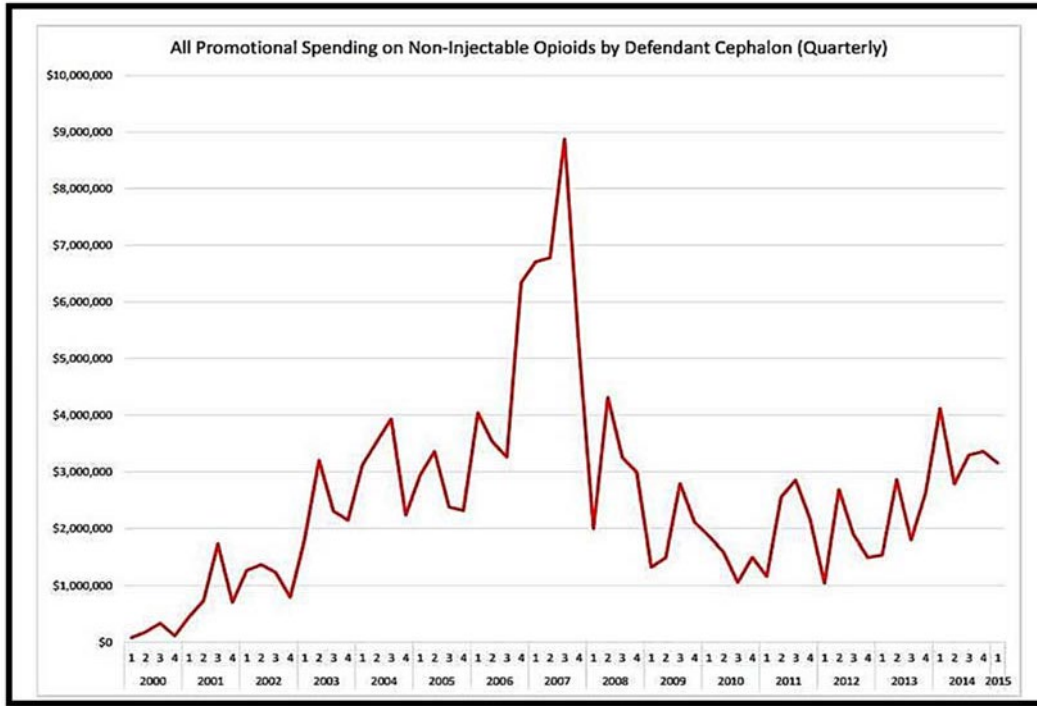
¹¹⁰*Id.* at 287.

representatives (also called “detailers”) and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Manufacturing and Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

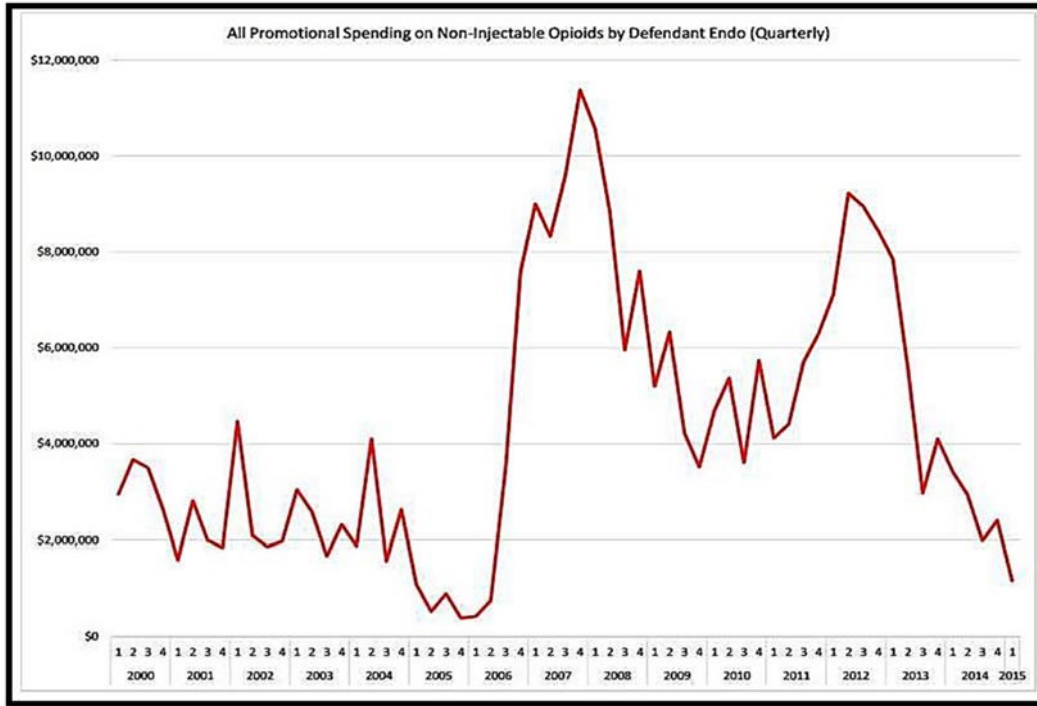
121. In accordance with common industry practice, the Manufacturing and Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

122. Manufacturing and Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing and Marketing Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing and Marketing Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

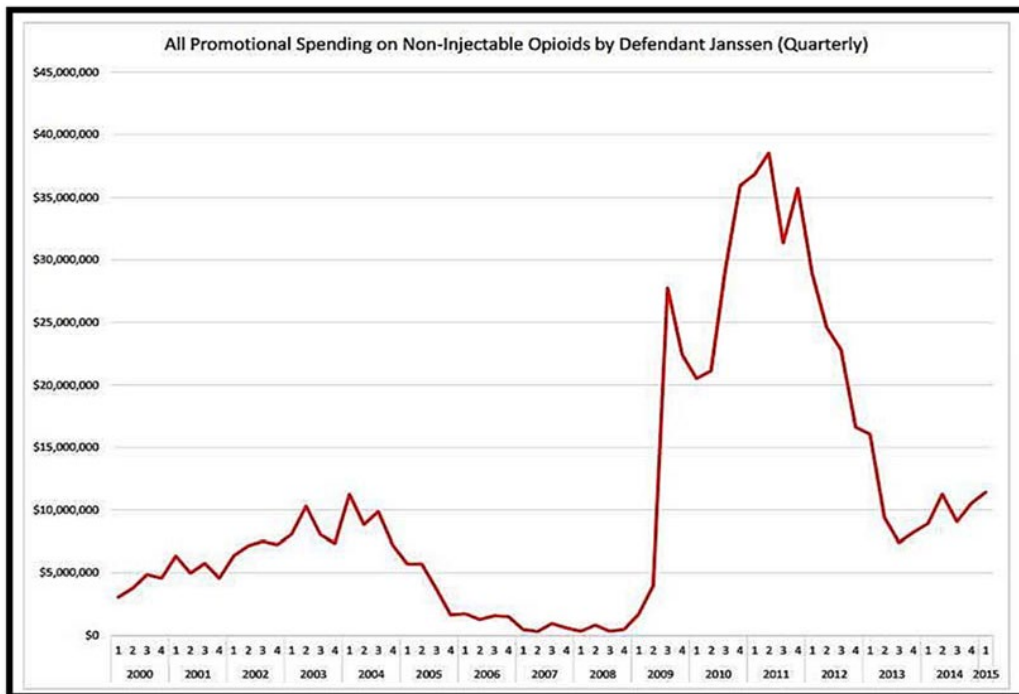
123. Teva’s quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:



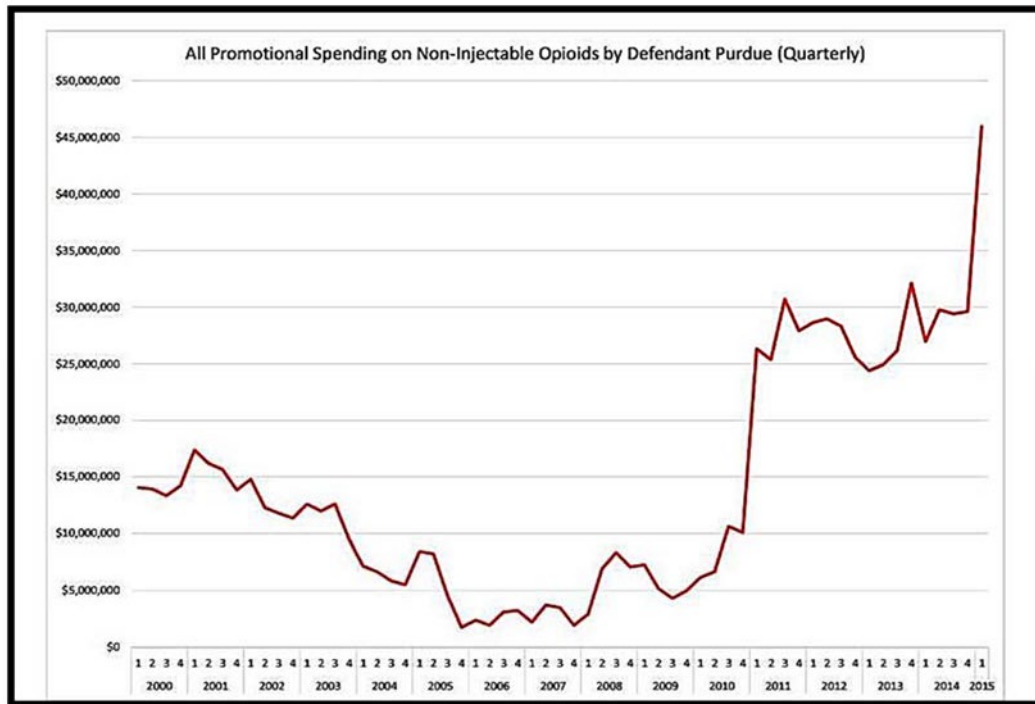
124. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year), as shown below:



125. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



126. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the DOJ, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continues to rise, as shown below:



127. Purdue also aggressively disseminated its messages to pharmacists—where they were told about high-volume prescribers that they should target. For example, a Purdue sales representative reported a Walmart pharmacist stating that “Dr. Kennedy is writing oxy with both hands. She rolled her eyes and told me it is doing very, very well,” and a Walmart pharmacist reportedly told Purdue “To talk with Dr. Secor. Big narcotic writer intown.”

128. For its opioid, Actiq, Teva also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

129. Thousands of prescribers attended Teva speaking programs. Teva tracked the

impact that these programs had on prescribing in the three months following the event and concluded that doctors' prescribing of Fentora often increased.

8. MANUFACTURING AND MARKETING DEFENDANTS
USED SPEAKERS' BUREAUS AND PROGRAMS TO SPREAD
THEIR DECEPTIVE MESSAGES

130. In addition to making sales calls, Manufacturing and Marketing Defendants' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturing and Marketing Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Manufacturing and Marketing Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Allergan, Janssen, Endo, Teva, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance, and other services.

9. THE MANUFACTURING AND MARKETING DEFENDANTS
DISSEMINATED THEIR MISREPRESENTATIONS
THROUGH THE PHARMACY DEFENDANTS

131. Pharmacy Defendants also worked in concert with opioid manufacturers to ensure that the false messaging surrounding the treatment of pain and the addictive nature of opioids was consistent and geared to increase profits for all stakeholders.

132. As the opioid crisis developed, the Pharmacy Defendants either knew or were willfully blind to the fact that the information being spread by the Manufacturing and Marketing

Defendants, including by them, was false. The Pharmacy Defendants knew this primarily because of the wealth of data they themselves collected, which allowed them to see patterns of prescribing, overuse, and diversion. The information they had was in addition to the more generally available information that Purdue had pleaded guilty to criminal misbranding of OxyContin in 2007 and had admitted that many of its marketing messages were false.

a. CVS

133. For example, as early as 2001, CVS worked closely with Purdue and its unbranded marketing arm, Partner's Against Pain to "fight back" against allegations (later proved to be true) that Purdue's OxyContin was being abused at alarming rates. It was Purdue's PAP website that Purdue, and its "Partners," including CVS, utilized to make the claims that the risk of addiction associated with OxyContin was very small.



Stephen L. Seid
Sr. Director, National Accounts
and Trade Relations
(203) 588-7315

TO: Jim Lang

FROM: Steve Seid

RE: CVS Pharmacy

DATE: May 11, 2001

Jim, on May 2, 2001 Don Tasser and I met with three of the key pharmacy people at CVS. They were:

- Barry Jasili, R.Ph., J.D., Director, Quality Improvement
- Susan DelMonico, R.Ph., J.D., Director, Regulatory Compliance
- Sharon Galzarano, R.Ph., Manager of Professional Practices

The goal of the meeting was to talk about mutually beneficial initiatives with CVS to improve education with their pharmacists. We also wanted to reiterate our position on ensuring availability of OxyContin® for appropriate patients. I think overall the entire meeting was very productive and the CVS people were extremely supportive.

Key issues discussed were as follow:

- 1 They were resolute in their commitment to good pharmacy practice. Part of that good pharmacy practice is ensuring availability of OxyContin for appropriate patients. Their goal is good patient care.
- 2 As a group they were vocal, particularly Barry Jasili, indicating that they felt that Purdue was in many ways being victimized by the situation. That the product is not the issue, but that the abuser is the issue. He indicated that, from his perspective, we should be fighting back even harder. We should be pointing out the benefits of our brand.
- 3 CVS will be sending out a copy of our Abuse and Diversion Brochure to 4,100 pharmacies. Our letter will be personalized for the CVS pharmacist and cosigned by Barry Jasili and Susan DelMonico. They will also be sending out a version of the Abuse and Diversion Brochure with their logo.
- 4 CVS will also put a copy of the Abuse and Diversion Brochure on their intranet site called RxNet.
- 5 They will be looking to utilize both of our written CE Programs, in particular, for new grads coming to work for CVS.
- 6 They talked about being more preemptive with our joint educational efforts. We will be setting up at least five programs at this time through CVS.
- 7 They talked about the possibility of co hosting programs in areas of healthcare professionals. I don't know if there was a unanimous agreement among the CVS people, but we will follow up to see if that is possible. Susan DelMonico will be the point person for CE Programs.

I believe we are garnering some significant support with CVS. Don Tasser will ensure follow up on these key programs.

134. Purdue worked together with CVS to ensure that CVS's own pharmacists were trained by Purdue on many of the misleading marketing messages that would later form the basis for a 2007 criminal guilty plea and \$600 million fine between Purdue and the DOJ for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential for abuse. CVS's ties to PAP were so deep that CVS even went so far as to put CVS's logo communications from its "partner":



CVS/pharmacy

June 2001

Dear CVS Pharmacists:

CVS is proud to participate in Partners Against Pain®, a therapeutic alliance of pharmacists, physicians, nurses, and pain experts, sponsored by Purdue Pharma. We acknowledge the legitimate concern of pharmacists over the diversion of opioid medications.

That's why we recently developed, and have enclosed, "How to Stop Drug Diversion & Protect Your Pharmacy." Included in this guide are such helpful tips from the U.S. Drug Enforcement Administration, such as:


- How to detect prescriptions that have been "rinsed" blank and rewritten
- Confirming prescriptions using a published phone number – not the number on the prescription – if you have doubts about any aspect of it

Treating people in pain is a top priority. Purdue is a leader in educating the healthcare community on effective pain management and the appropriate use of pain medicines. Why? Because we believe that education and open communication are keys to effective pain control.

Along with hundreds of educational programs and brochures, Partners Against Pain sponsors the award-winning website – www.partnersagainstpain.com – which provides pain information, assessment tools, and support – 24 hours a day. We hope you and your customers will visit this site, and that the enclosed brochure will help you in your efforts to serve your customers and protect your pharmacy from drug diversion.


Provide the right patients, with the right pain medicine, at the right dosage, under the right supervision. Together, let's treat the pain. Please share a copy of this letter with your technician.

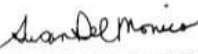
Sincerely,


Dr. Robert F. Reder, V.P.
Medical Affairs & Worldwide Drug Safety
Purdue Pharma L.P.

cc: Philip Keough, R.Ph.
Director, Pharmacy Operations

Sharon Galzarano, R.Ph.
Manager, Professional Practices


Barry Jasilli, R.Ph., JD
Director, Quality Improvement
CVS Corporation


Susan DelMonico, R.Ph., JD
Director, Regulatory Compliance
CVS Corporation



One Stamford Forum, Stamford, Connecticut 06901-3431 Telephone (203) 588-5000 Fax (203) 588-9850
www.partnersagainstpain.com

135. CVS was so eager to ally itself with Purdue and its profits that it solicited Purdue for participation in co-hosting continuing education programs for healthcare providers and pharmacists regarding training on diversion of prescription opioids.



*Request for Support:
CVS "Quality First™ Communication Skills"
Continuing Education Program*

Over the last decade, and continuing today, pharmacy practice has evolved dramatically. As part of this evolution, we have witnessed a pharmacist's role change from one of a dispenser of products to that of a supplier of information, deliverer of medication, clinical reviewer of drug therapy, and even disease state manager. In order to be prepared for this enhanced role, we must continue to educate our pharmacists on the importance of superior communication skills, especially in light of new, often aggressive therapies, including that of pain management therapy. These communication skills are not limited to patients, and apply just as significantly to interactions with other health care professionals. We all recognize the challenges that often accompany community practice, and thus we must also educate pharmacists and technicians on topics that include time efficient patient counseling, and even conflict resolution.

We have always enjoyed a positive relationship with Purdue Pharma, and most recently our productive and pleasant interactions with Mr. Stephen Seid and Mr. Donald Tasser, have allowed us to work together to share the informational brochure entitled "*How to Stop Drug Diversion, and Protect Your Pharmacy*" with our pharmacists. This joint initiative was advantageous to both of our organizations. Based on this success, and our productive history with Purdue, we are offering what we believe will be another mutually beneficial opportunity. As part of our Quality First™ program, a comprehensive program that addresses quality related issues, we are hosting a series of Continuing Education sessions for our pharmacists. This series will contribute significantly to our strategic business goals, and thus we anticipate nearly 100% attendance by our pharmacists. This program is considered a critical part of our business plan, and thus we'll be presenting and promoting it at our annual Operations/Marketing Conference in Nashville, this September.

In Nashville, our Regional Healthcare Managers (who are all pharmacists) will be trained by Dr. Daniel Teat, of Campbell University School of Pharmacy, who has designed a multiple-hour Communication and Conflict Resolution CE program, and Barry Jasilli, R.Ph., J.D. Dr. Jasilli has produced a three-hour CE that addresses prescription accuracy. Incorporated into the CE would be examples (role playing opportunities) of how to handle situations which are often associated with Purdue's products. By way of example: how to communicate effectively with patients and physicians about appropriate pain management therapy, and how to resolve potential conflict with a drug "seeker".

136. One would have to seriously question the accuracy of any training CVS pharmacists received from Purdue and Partners Against Pain on abuse and diversion, yet there has been no evidence that CVS undertook any measures to re-educate its pharmacists on how or why Purdue and PAP training might be lacking in the area of diversion and abuse of opioids.

137. CVS's role was not limited to expanding the market for prescription opioids. CVS worked hard to ensure that demand for prescription opioids was not only sustained but multiplied.

138. It did so through its marketing, advertising, and promotion efforts both on its own and in concert with other stakeholders.

139. Contrary to what CVS has stated under oath in written discovery before this Court, CVS helped to grow the demand for prescription opioids by participating in the marketing, advertising, and promotion of opioid products with and on behalf of opioid manufacturers.

140. CVS's marketing and promotion of opioids was not limited to its involvement with Purdue and Partners Against Pain. CVS did not draw lines when it came to promoting opioids, and there were no brand boundaries.

141. One example can be found in CVS's work with Endo to increase patient adherence to continuing their use of opioids. In fact, CVS's role in the promotion of Endo's Opana ER was so important that it was described as having a crucial role in carrying out one of key sales tactics in Endo's 2012 Business Plan.

142. Through a company called Catalina Health ("Catalina"), Endo Pharmaceutical helped Endo to target OxyContin patients in areas where Opana ER, a highly abused opioid manufactured by Endo, had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on their opioids. CVS, through its pharmacy retention programs, sent letters to the patients' homes to encourage them to stay on Opana – even though prolonged use of opioids increases the risk of addiction, and even though patients in pain presumably need no reminder to continue to take their pain medications. CVS formalized its agreement to promote, market, and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service."

143. Under this Agreement, CVS not only contractually agreed to promote Opana ER to its customers (patients) at the point of sale, but it even insisted upon reviewing and **approving** the specific messaging used.

144. Similarly, CVS contracted with Endo to **prepare** and disseminate materials promoting OpanaER nationwide.

145. CVS likewise helped Allergan promote its opioids by participating with Cardinal's Marketing and Business Development team in programs designed to offer rebates and off-invoice discounts on products, with the aim being to "move []product."

Beneficial for both new and existing products, the RxDeals offering is customized to meet your unique needs and is designed to provide special offers – rebates or off-invoice discounts – to retail chain and independent pharmacies, including CVS and Walgreen's, to help move your product.

Contact your Marketing and Business Development Sales Representative today and RxDeal your way to maximizing your sales!

[»View this week's Service **Flash**](#)

Thanks and have a great week!

The Marketing and Business Development Sales Team

Jeff Foreman, RPh
Vice President, Strategic Purchasing / Branded Purchasing
Office: 614.757.6674
jeff.foreman@cardinalhealth.com

146. Marketing, advertising, and promoting opioids was not a new practice for CVS. In fact, CVS had been advertising these activities to manufacturers for years. For example, CVS made at least one pitch to Insys, a company whose senior executives were recently criminally convicted for their unlawful marketing of opioids, to help sell its incredibly potent opioid, Subsys, a liquid form of fentanyl.

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Patient and Pharmacist Educational Services

All programs must be approved through the CVS Caremark internal approval process prior to execution. The materials accompanying the programs and services described will be limited to the extent permitted by and in compliance with applicable laws, including federal and state privacy laws.

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147. CVS touted the reach of its communications and explained the science behind its sophisticated marketing, advertising, and promotional services.

■ Pharmaceutical Services

**Get the
medicine
Right.....**



**...with the right
educational communications.**

- NewScript Rx
- Clinical FoCVS
- Rx Literature Display
- Rx Edge®
- CareCheck Plus
- ExtraCare

**Communicate your product's unique clinical benefits to
thousands of targeted individuals.**

2

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■ Pharmaceutical Services: Overview



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148. Hardly novices, CVS recognized its expertise in ensuring that opioid manufacturers like Insys were able to reach their intended market by using CVS's promotional programs which are designed to "deliver results."

■ Where We Can Help

- Access to appropriate audience
- Clinical expertise and resources
- Identifying patients who may benefit from your product
- Increase awareness of new treatments or therapies
- Service excellence
- Broad and integrated overall reach



The expertise, tools and vision to deliver results.

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149. Through CVS's NEWScript program, CVS claimed to be perfectly poised to assist with new product launches and a truly impressive reach.

■ NewScript: hard copy & electronic

CVS NEWScript:

Designed for new product launches.

Prepares pharmacists for first scripts to arrive.

- Brief summary (one page) authored by CVS' Clinical Department
- Designed to create immediate pharmacist awareness of brand launch.
- Publication is strategically timed-typically 1 week prior to product arriving at store
- Published in hard copy format and soft copy format as follows:
 - Hard Copy distribution to entire chain via red bag delivery (internal delivery system)
 - ~ 7,300 stores, ~23,000 pharmacists
 - Posted to CVS Intranet site (RxNet)
 - Email communication to stores with link direct link to RxNet NEWScript
- Lead time is 4 weeks
- Base cost: \$40,000 (addl options available)



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b. Walgreens

150. Working with Purdue as early as 2001, Walgreens played a pivotal role in expanding the market and ensuring the demand and supply for prescription opioids would grow to tragic proportions. Purdue was particularly interested in using what Walgreens described to Purdue as its Regional Level Market Programs to educate pharmacists and patients on the benefits of Purdue's OxyContin.

should have an answer on this shortly.

- During our discussion on educational programs, Sheila indicated the importance of coordinating our educational efforts. There has been a lot of recent demand from the field for Walgreens' district level programs.
 - o Sheila volunteered the fact that it is much wiser for us, and cost effective, to do, what she called, Regional Level Market Programs. She indicated that instead of getting 30 or 40 pharmacists at a time, a Market Program would get 250 – 300 and address a market as opposed to just one district.
 - o There continues to be the need to get the message out to the field that it is important to communicate their needs for chain programs through National Accounts so that we can support that effort. Action: Tony Scifo will be following through with Sheila and Dawn DiLullo, who is in Trade Relations and Pharmacy Recruitment and works on these regional programs.
- The key person at the field level, for us, is the Rx Supervisor. The Rx Supervisor reports to the local District Manager for Walgreens. The District Manager is more concerned about the front end business. The Rx Supervisor is responsible for everything behind the counter.
- Tony Scifo suggested that it would be of value for us to do programs for the above Rx Supervisors. There are 135 to 140 of these individuals. This would be a good opportunity to educate those who influence hundreds of pharmacists. **Action:** Tony Scifo to follow up with Sheila Bennett.
- Walgreens also sends out educational modules to their pharmacy staff. One of the ones that has been proposed is a pain module. **Action:** Tony Scifo is working with Dawn DiLullo to see if we can support her efforts in the development of that module.
- There have been some questions from the field as to actions taken by Walgreens' pharmacists as it relates to the dispensing of OxyContin. This has become an issue in the diversion areas.
 - o This discussion was handled generically without identifying specific situations.
 - o The local pharmacists are expected to follow corporate direction, but Walgreens respects the Pharmacists obligation to pharmacy practice. Therefore, within legal, ethical, and corporate guidelines the individual pharmacist is expected to make pharmacy practice decisions using their best judgment.

151. In fact, Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into Walgreens “corporate guidelines” to which Walgreen’s pharmacists were “expected to follow” when it came to the dispensing of prescription opioids.

152. Walgreens also used its corporate oversight abilities to identify stores it believed were not filling enough oxycodone to make sure they weren’t “turning away good customers” and encouraging stores to utilize continuing education created by opioid manufacturers to inform their decisions regarding dispensing.

153. Starting in at least 1999, Purdue sponsored Walgreens’s Pharmacy’s continuing education programs designed to encourage stores to “get on the Pro Pain Management Band

Wagon.” Purdue was thrilled with the response and assistance it received from Walgreens when Purdue presented on “Pain Management for the Pharmacist.” At the beginning of each Purdue sponsored meeting, a Walgreens pharmacist made a presentation on his store and the program implemented. His store actively advertised to area doctors and patients that they were a “full-service” pain management pharmacy. This service included providing a list to physicians’ offices of all Schedule II opioids they had in stock (and they had everything), accepting “verbal orders” for Schedule II opioids prior to presentation of the original prescription at the store to decrease “waiting time,” allowing partial fills on Schedule II opioids for terminal patients, and accepting after hours “emergency CII prescriptions” without a hassle. Purdue praised the pharmacist’s actions as “fantastic.”

154. Walgreens’s use of pro-opioid continuing education continued as the opioid crisis grew. For example, Walgreens’s Market Director of Pharmacy Operations recommended that Walgreens District Managers and Pharmacy Supervisors attend a continuing education program titled “The Pharmacists’ Role in Pain Management: A Legal Perspective,” which was available on-line. This program was one in a long line of pharmacist continuing “education” programs, or CEs, that opioid manufacturer Purdue developed as part of its strategy to disseminate “a new school of thought” about opioids. Through these programs, Purdue and the Pharmacy Defendants disseminated fraudulent information in an effort to correct pharmacists’ “misunderstanding” about pain patients and the practice of pain management. Purdue took what it called an “aggressive role” in the education of Walgreens’s and other pharmacists on pain management issues.

155. Walgreens’s Market Director of Pharmacy Operations also recommended a second continuing education program titled “Navigating the Management of Chronic Pain: A

Pharmacist's Guide." The second CE incorporated into Walgreens's dispensing training program, "Navigating the Management of Chronic Pain: A Pharmacist's Guide," was sponsored by opioid manufacturer Endo Pharmaceuticals and disseminated manufacturer messaging designed to broaden the market for opioids. For example, it stated "according to most reports, approximately 30% of the population lives with chronic pain" and citing, *inter alia*, another CE presentation sponsored by the American Pain Society (another known front-group). It also claimed that "most opioid adverse effects can be managed with careful planning and patient education." It went on to discuss "fears and prejudices" related to addictive behaviors that "unnecessarily limit" opioid use, described as "opiophobia," which the piece claimed was the result of "misunderstandings regarding the concepts of addiction, physical dependence, and tolerance."

156. One of the presenters for this Endo sponsored CE was Kenneth C. Jackson. Jackson was a frequent speaker and Key Opinion Leader ("KOL") for Purdue, and he also co-authored the CE program titled "Use of Opioids in Chronic Noncancer Pain," which was sponsored by Purdue. Released in April 2000, it was designed to eliminate "misconceptions about addiction, tolerance and dependence" and contained many of the same messages as the pharmacist guide he authored.

157. Walgreens also presented the video "The Pharmacist's Role in Pain Management- A Legal Perspective" at mandatory meetings for pharmacy managers. This continuing education program was also sponsored by Purdue, was similar to the earlier presentations, and was further disseminated to Walgreen's pharmacists in June 2011. Released in 2009, the program was presented by Jennifer Bolen, JD. Bolen was a frequent speaker for Purdue and other opioid manufacturers, served as Special Counsel for the American Academy of Pain

Medicine (a known Front Group for opioid manufactures), acted as a KOL for Purdue, and was described by Purdue as “a pain patient who takes opioids.”

158. Armed with information gleaned from a Purdue-sponsored CE, the Walgreens pharmacists who had temporarily stopped filling controlled substance prescriptions began to accept them again. It is no surprise that in 2013 Walgreens acknowledged that several of the stores that touted this CE as part of their controlled substance action plan dispensed “certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA.”

c. Walmart

159. Purdue described Walmart as its “trade partner” in “Winning the War” for continued “Oxy/Contin” distribution.

160. Walmart requested, and Purdue provided, pharmacist CE programming, including presentations titled: “Use of Opioids in Chronic and Cancer and Non-Cancer Pain Management: The Myths and Realities”; “New Trends in the Use of Opioids in Pain Management”; and “Lawful Prescribing and the Prevention of Diversion.”

161. As another example, on July 9, 1996, Purdue held a “Wal-Mart Pain Management Symposium.” Broadcast live via satellite to 2,500 stores nationwide with videotape copies sent to each Wal-Mart store, the speakers included Henry Freedy, Pharm. S., and Neil Irick, MD.

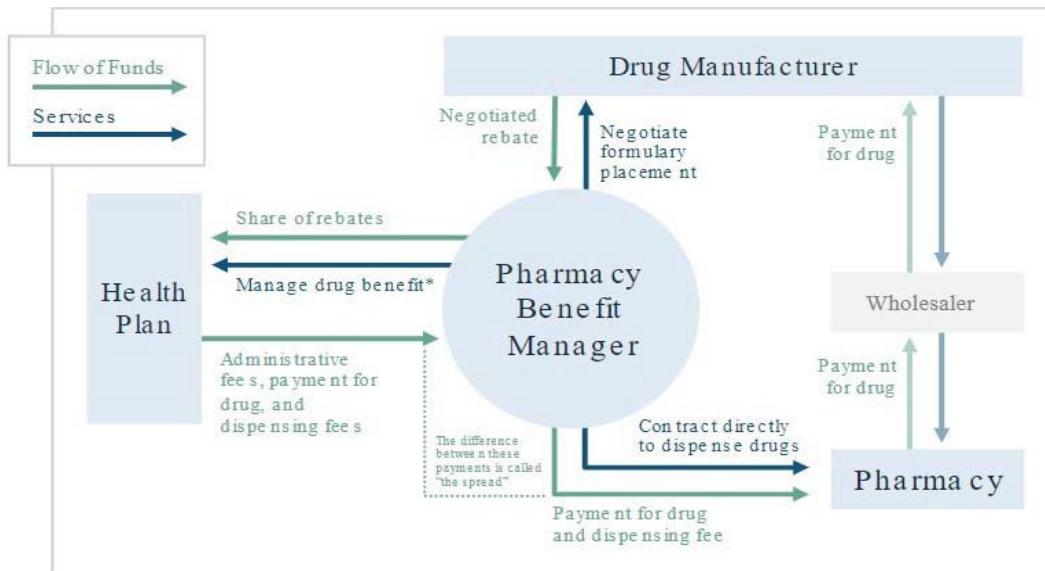
162. These presentations were accompanied by thousands of dollars in “unrestricted grants” from Purdue to Walmart.

10. THE MANUFACTURING AND MARKETING DEFENDANTS
DISSEMINATED THEIR FRAUDULENT MESSAGES
THROUGH PHARMACY BENEFIT MANAGERS

163. Pharmacy Benefit Managers (“PBMs”) are companies that are contracted manage the pharmacy benefit portion of plans offered by insurers. One of the services the PBMs provide is to create standard, national formularies and utilization management (“UM”) programs. The PBMs offer these standard formularies and UM programs to their clients. In crafting these standard formularies and UM programs, PBMs review and make determinations regarding which medications are effective or appropriate. PBMs also review and pay claims for the drugs dispensed to what they refer to as their “covered lives”—*i.e.* the plan participants and beneficiaries whose lives and health are insured through insurers and other entities who contract with the PBMs. As a result, PBMs exert significant influence over prescriptions dispensed in the United States, including influencing the quantity, dosage strength, duration, and refill availability for each prescription.

164. Although PBMs contract with insurers to provide pharmacy benefit management services, they also contract with drug manufacturers and with pharmacies, including opioid manufacturers and pharmacies. They are paid by their clients to make safe and effective drug therapies available to their covered lives. But, as described herein, they are also paid by drug manufacturers to provide the greatest access to their products, so as to increase sales, with little to no regard for safety or efficacy. And they are paid by the pharmacies where the plan participants and beneficiaries’ prescriptions are filled, to verify coverage but also to assist the pharmacy in ensuring that a prescription is appropriate.

165. This chart illustrates the central role the PBMs play in the prescription drug market:



166. The FTC is currently investigating the PBM industry, and there is general bipartisan agreement that “PBMs operate with little to no transparency, making it very difficult if not impossible to understand the flow of money in the prescription drug marketplace and how PBMs determine the prices for, and impact the cost of, prescription drugs.”¹¹¹ Vertical integration in the PBM industry is also in the spotlight, as “CVS/Caremark, OptumRx, and Express Scripts control roughly 75% of the PBM market and are vertically integrated with insurers Aetna, United Healthcare, and Cigna, respectively.”¹¹² These three PBMs (CVS/Caremark, OptumRx, and Express Scripts) are referred to as the Major PBMs.

167. The Major PBMs are, and, at all relevant times were, in a position to influence prescribers. In order to leverage this influence, the Manufacturing and Marketing Defendants enlisted the Major PBMs in their marketing campaigns. The Major PBMs assisted the

¹¹¹ Letter from Senators to The Honorable Lina Khan, https://www.grassley.senate.gov/imo/media/doc/grassley_cantwell_colleagues_to_ftc_-_pbm_investigation.pdf (Jan. 22, 2024).

¹¹² *Id.* (citations omitted).

Manufacturing and Marketing Defendants in disseminating false marketing in two ways: first, they assisted in creating or disseminating marketing materials containing the manufacturers' false messages; and second, their research and data affiliates created "studies" and materials the manufacturers could use in their marketing.

168. As the opioid crisis developed, the Major PBMs either knew or were willfully blind to the fact that the information being spread by the Manufacturing and Marketing Defendants, including by them, was false. The Major PBMs knew this, actually or constructively, primarily because of the wealth of data they had – information on every opioid prescription filled by all the beneficiaries of all of their client insurance providers, none of which had access to the aggregate information about prescribing, overuse, diversion, and addiction that the Major PBMs had. The information they had was in addition to the more generally-available information that Purdue had pleaded guilty to criminal misbranding of OxyContin in 2007 and had admitted that many of its marketing messages were false.

169. Starting in the late 1990s, the Major PBMs partnered with Purdue and other opioid manufacturers to spread false information about opioids in order to increase opioid sales and expand the market.

170. For example, in 1999, Medco (Express Scripts' predecessor) arranged for its pharmacists to be trained by Purdue's speaker consultants regarding chronic pain management and the use of OxyContin.

171. In 2003, internal Purdue documents show "[o]pportunities have been presented by Medco to work more closely with targeted clients within the marketplace on a client-by-client basis." These "opportunities" included developing educational programs to "stave off any formulary restrictions" and disseminating Purdue-created "educational" materials—including

“New Perspectives on the Pharmacology of Opioids and Their Use in Chronic Pain” and “Drug Diversion and Abuse: The Facts, Legal and Ethical Issues Affecting Pain Management: FactorFiction.” Purdue provided this information to Medco to “be used with employers and managed care plans on the appropriate utilization of [Purdue’s] products.”¹¹³

172. During these same years, along with Medco, Express Scripts was also one of Purdue’s largest customers. Notably, Medco and Express Scripts remained Purdue’s largest customers for OxyContin for the years up to and following the 2012 merger of these companies.

173. And in similar fashion to Medco, Express Scripts also worked directly with Purdue in the critical years of OxyContin growth to expand the pain treatment market through the dissemination of misinformation about the use of opioids to treat chronic non-cancer pain.

174. For example, in 2000 and 2001, Express Scripts worked together on numerous programs to disseminate “educational” materials to tens of thousands of patients and high prescribers of OxyContin advocating for opioids in chronic pain treatment and downplaying the risks of addiction. These programs included Express Scripts engaged in mass mailings of Purdue created propaganda such as “Dispelling the Myths about Opioids,” “The Impact of Chronic Pain: An Interdisciplinary Perspective CME booklet,” “Overcoming Barriers to Effective Pain Management,” and “Use of Opioids in Chronic Noncancer Pain CME booklet.” These documents contained false information downplaying the risk of addiction and promoting the use of opioids in long term chronic pain treatment.¹¹⁴

175. In one particularly telling internal Purdue “call note,” a Purdue executive

¹¹³SUPPLEMENTAL AND AMENDED ALLEGATIONS TO BE ADDED TO PLAINTIFF’S COMPLAINT AND JURY DEMAND. 1:17-md-2804, [Doc. 5716]. *Id.* at page 121.

¹¹⁴*Id.*

discussed “developing a piece on Opioid guidelines, [New England Journal of Medicine (NEJM)] quotes, and addiction terms.” Notably, the “NEJM quotes” likely refer to the one-paragraph Porter & Jick letter discussed above that was published in the *New England Journal of Medicine* reporting an observed low rate of addiction in patients prescribed opioids for short periods in an in-patient hospital setting. The Purdue executive continued: “[l]egal has stated that [Purdue] representatives cannot utilize this [NEJM] piece. My thoughts are that this piece may be sent out by Express Scripts. Express Scripts and Purdue could target [family practitioner physicians and internal medicine physicians] who are the high writers of [DEA Schedule II and III drugs]. The mailer was intended to educate the physician on the beneficial uses of OxyContin and the preferred formulary status.”¹¹⁵

176. A number of these joint programs between Express Scripts and Purdue were prompted by Express Scripts’ desire to work with Purdue to address the negative attention that OxyContin was receiving related to abuse and diversion in the early 2000s. For example, a March 14, 2001 letter from Express Scripts to Purdue explained “[c]learly with the market turbulence surrounding OxyContin you and your organization have significant demands on your time . . . there are several strategic initiatives where Express Scripts can support Purdue Pharma in your efforts to educate the market on the prescribing, administration and consumption of OxyContin.”¹¹⁶

177. These “strategic initiatives” proposed by Express Scripts included sending 15,000 “targeted” mailings to physicians which included a letter written by Express Scripts’ Medical director summarizing key principles of the Purdue Front Group, American Pain Society,

¹¹⁵/d at page 122.

¹¹⁶/d at page 123..

and included the Purdue-created brochures “The Patient Bill of Rights for Pain Management” and “Dispelling the Myths about Opioids” which contained misinformation about OxyContin risks, such as “addiction risk also appears to be low when opioids are does properly for chronic noncancer pain.”¹¹⁷

178. An April 2001 Purdue memo further described the reasons behind Express Scripts and Purdue’s collaborations at that time: “[Express Scripts] has told us that this mailing is necessary so that [Express Scripts] may squelch the anti-OxyContin pushback from their clients (Managed Care Organizations and Employer Groups) due in large part to the national media attention OxyContin is receiving.”

179. Purdue’s and Express Scripts’ joint efforts to expand the opioid market continued in the summer of 2001, when they used an Express Scripts “proprietary database” to identify the top 1,900 physicians with high prescribing rates for Schedule II narcotics and then mailed these 1,900 physicians materials created by the Front Group American Pain Society. The mailed APS material promoted use of pain scales and the now debunked, industry-advocated concept of pseudo-addiction.

180. Express Scripts and Purdue’s collaboration continued through 2004, when Express Scripts and Purdue developed a series of pain management presentations for Express Scripts’ clients, to be conducted by Purdue’s Medical Liaisons, who were doctors and medical professionals employed by Purdue to promote opioid therapy.

181. During these same years, Purdue also conspired with Optum to spread misinformation about the use of opioids to treat chronic pain and the risks of opioid addiction.

¹¹⁷*Id.*

One example occurred in February 2003, when UnitedHealthcare (“UHC”) and OptumInsight met with Purdue to give a presentation on “Managing Chronic Pain Associated with Lower Back Pain.” The goal of this presentation was to develop a comprehensive plan between Purdue, UHC, and OptumInsight to re-educate physicians on opioid use for the treatment of chronic pain and low back pain. The program included “[t]argeting physicians not aligning with UHG clinical objectives [for treating chronic pain] to modify behavior.”¹¹⁸

182. As a result of this meeting, in 2004 OptumInsight and Purdue executed a Master Services Agreement to roll out this program in 2004-2005. The program would include Purdue, UHC, and OptumInsight working together to identify physicians from UHC and Optum Insight’s database and then developing comprehensive education materials on the effectiveness of opioids in chronic pain treatment to send to these physicians.

183. OptumInsight and Purdue delivered this information through a series of teleconferences, newsletters, faxes, live meetings, case study monographs, letters, and website and web-based programming directly to physicians.

184. The project, referred to as the United Healthcare Physician Education program, included the following false and misleading messages targeted at UHC prescribing physicians:

- a. Opioid use is associated with some moderate side effects, but the risk of drug dependence is low;
- b. Concerns about abuse, addiction, and diversion should not prevent the proper management of chronic and low backpain;
- c. Opioids are the most effective way to treat pain;
- d. Opioid addiction does not occur in the chronic pain patient; and
- e. Certain signs of dependence that sometimes can be confused with addiction are actually “pseudo-addiction.

¹¹⁸*Id* at page 124.

185. To assist in the marketing efforts of opioid manufacturers, the Major PBMs have for years provided multiple opioid manufacturers with lists of all their plan clients as well as the names of physicians who were participating in the plan's provider networks. The manufacturers used this information to target the highest opioid prescribers with pull-through marketing.

186. For example, according to one 2011 email, Endo sales representatives were instructed to "[m]aximize pull-through with key managed care plans," "[d]rive brand awareness across top [Opana ER] prescribers," and promote favorable Opana ER formulary positioning. Sales representatives were also told to focus on providers "that have the most potential" and not "waste time" on other physicians. Sales representatives also were dispatched to (and did) promote Opana ER formulary status to prescribers.¹¹⁹

187. In another example, after Endo had negotiated favorable formulary placement with Optum in 2010, sales representatives were told to "present the great information" to prescribers and take advantage of the Opana ER "opportunity" for "pull through" sales.¹²⁰

4. Only when all this is done should you present the great information that now, OPANA ER is 2T, Lowest Branded Co-Pay for UHC Commercial (and Part D) patients! Get commitment first that OPANA ER is the right choice...then show how easy it is to provide OPANA ER for these patients!

188. In 2011, a senior account executive at Purdue asked California district managers to implement a "Push-Up initiative" aimed at "Butrans subscriber advocates" who can "help gain Preferred tier status for Butrans rather than 3rd tier status," "removing a prior authorization or step therapy," or "alleviating a burdensome PA requirement to something that is more

¹¹⁹/d at page 125.

¹²⁰/d at page 126.

acceptable.” The initiative identified plans “associated with national PBM’s Caremark and ESI” as “great targets.”¹²¹

189. Upon information and belief, the PBM Defendants entered into rebate agreements with Manufacturers, the rebate agreements between the Manufacturers and the Major PBMs not only incentivized high prescribing but also strongly disincentivized quantity limits on opioids.

190. In addition, beginning in 2006, Express Scripts and Purdue entered into an ongoing “Participating Manufacturer Agreement” under which, in return for “administrative fees,” Express Scripts agreed it would provide numerous deliverables to Purdue which enabled Purdue to more effectively pull through its drugs’ formulary status to physicians. The “administrative fees” Express Scripts received were tied to the number of opioids it sold—*i.e.*, the more opioids it sold, the more it was paid. This agreement was strictly confidential. Express Scripts and Purdue renewed this agreement on at least three occasions, and it was in place until at least the end of 2010.¹²²

191. For years, the Major PBMs also entered into rebate contracts with Purdue and other opioid manufacturers that included standard language expressly conditioning rebate eligibility on the absence of meaningful quantity limits for prescription opioids.

192. By at least 2009, and for several years thereafter, Express Scripts published a “Disease Strategy-Pain” white paper that it described as a summary of its “comprehensive strategy [of] how we manage pain.” This white paper was used to answer client questions about opioid programs, including questions asking why Express Scripts did not have prior

¹²¹*Id* at page 126.

¹²²*Id* at page 128.

authorizations in place on OxyContin. Under the heading “Clinical Considerations,” the paper stated that, with respect to “chronic opioid therapy,” addiction was “uncommon.”¹²³

193. In 2011 and 2012, Express Scripts and Purdue collaborated on false and misleading guidelines for workers’ compensation patients to promote “safe and effective chronic opioid therapy.”

194. In fact, as late as 2017, Express Scripts gave educational presentations on pain management that treated the risk of addiction to opioids as minimal. In a presentation regarding “The Management of Persistent Pain in Older Persons,” Express Scripts Vice President Andrew Behm asserted that psychological dependence to narcotic analgesics was “rare” and that “Addiction associated with the appropriate use of opioid analgesics is uncommon.” The presentation also described “physical dependence” as “common” and a “state of adaptation to chronic opioid therapy,” and recommended fentanyl for chronic pain in older adults.¹²⁴

195. Similarly, Caremark published an “Opioid Prescriber Toolkit,” a lengthy document targeting doctors. As late as 2016, while acknowledging the existence of the opioid epidemic, Caremark’s Toolkit continued to spread misinformation about the safety of opioids for the treatment of chronic pain, stating, “Opioids can be safe and effective to treat pain when appropriately prescribed and monitored,” and including sample “opioid pain care agreements” to use with patients and other “tools” designed to provide assurance that opioids could be safely prescribed for long-term use. The Toolkit emphasized that “Chronic pain is a common public health problem in the United States” and promoted the use of opioids for the treatment of neuropathy, fibromyalgia, “persistent pain in older persons,” and migraines. Moreover, the

¹²³*Id.*

¹²⁴*Id.*

Toolkit included the guidelines published by Front Groups APS and AAPM in 2009, describing them as “an evidence-based guide for practitioners and regulators to help foster a medical practice environment where the judicious use of opioids may be used to reduce suffering from chronic pain.” Caremark’s Toolkit also asserted that it is difficult to disentangle opioid abuse, which would militate in favor of terminating opioid treatment, from tolerance, which could militate in favor of increased dosage or frequency of opioid treatment, and endorsed the concept of pseudo-addiction. Finally, the Toolkit provided patient handouts that downplay the risks of addiction, with statements such as the following, meant to reassure patients worried about the risk of addiction:

- “Opioid pain medicines, or simply opioids, have been used for hundreds of years to relieve pain.”
- “Many patients fear becoming addicted to opioids. Addiction and physical dependence are not the same.”
- “Most people will not become addicted to their prescribed pain medicine.”

196. The patient handouts listed the most common side effects of opioid therapy as constipation, drowsiness, nausea, vomiting, and itching. At the same time, the patient handouts warned of the dangers of taking acetaminophen, stating, “Using too much acetaminophen can cause liver damage. ... The effects of liver damage can range from feeling nauseous or ill to permanent liver damage and possibly death.”¹²⁵

197. OptumRx also participated in a Purdue advisory board in 2013 for the “abuse deterrent” version of OxyContin, which was focused on payors in managed care. In 2016, OptumRx conducted studies for Purdue to assess the economic impact of reformulated OxyContin.

¹²⁵*Id* at page 129.

198. OptumRx affiliates also marketed their data analytics capabilities to Purdue for research projects related to opioids, proposing, for example, to sell medical and pharmacy claims data from its “Cliniformatics DataMart” to Purdue, to study patient disenrollment in Medicare Advantage plans that discontinued coverage of OxyContin ER, and to research overdoses associated with OxyContin.

199. In addition to assisting the Manufacturing and Marketing Defendants in spreading false information about opioids, for years the Major PBMs and their affiliated companies provided the manufacturers with data, research, and consulting services needed to expand the opioid market.

200. For example, in the late 1990s and early 2000s, Express Scripts’ affiliate research entity, Practice Patterns Sciences, Inc. (“PPS”), and Medco’s Institute for Effectiveness Research provided research and studies for Purdue to aid its efforts to expand the opioid market. One example occurred in 2001, when Express Scripts/PPS developed a study for Purdue on “The Value of OxyContin Therapy in Patients with Moderate to Severe Pain due to Osteoarthritis.”

201. In addition, since the late 1990s, Express Scripts and/or its subsidiaries also played multiple roles in Purdue’s and Endo’s respective patient assistance program (“PAP”) marketing schemes. Express Scripts’ importance is evident in, for example, a 1996 email outlining how Purdue’s “IPAP usage[sic] has sky rocketed since [Purdue] instituted the Express Script policy,” and noting that “utilization has nearly quadrupled [sic].”¹²⁶

202. Express Scripts was integral to these manufacturer-PAP programs in constructing the program requirements and administering the programs themselves. Express

¹²⁶*Id* at page 130.

Scripts also used these programs to reach out to prescribers and patients directly to disseminate Purdue- and Endo- created materials.

203. Express Scripts' administration practices related to Purdue's and Endo's PAPs helped make their respective programs into very successful marketing tools to increase opioid use, drive volume, and facilitate access to opioids—including OxyContin and Opana—resulting in Express Scripts filling 1+ million opioid prescriptions and dispensing 100+ million opioid pills throughout the country through these PAPs. As an illustration, in the early 2000s, Express Scripts was enrolling over 3,000 new patients per month for Purdue's PAP. Moreover, from at least the early 2000s, Express Scripts knew or should have known about the ongoing and growing misuse and diversion of opioids, and/or that its opioid PAP work was causing opioid over-prescribing, over-dispensing, addiction and/or abuse.

204. The Purdue and Endo PAPs, and Express Scripts' administration and dispensing practices relative to them, raised numerous red flags, including dispensing large amounts of opioids to individuals, failing to conduct proper due diligence on patients, inappropriately recording deaths, and rerouting prescriptions to circumvent state law requirements.

205. For example, in 2010, Purdue audited Express Scripts' administration of the PAP program and found numerous failures by Express Scripts to properly vet IPAP applicants, including failure to verify patient-doctor relationships, failure to notice obvious inconsistencies in applications, and failure to process IRS information to determine its accuracy and legitimacy. In fact, Purdue found that during a period of just a few months in 2010, Express Scripts dispensed more than 17,000 OxyContin pills to fraudulent PAP enrollees/applicants. Similarly, a 2010 email exchange between Purdue and Express Scripts employees outlined how a Purdue PAP patient was reportedly "selling [his PAP opioid prescriptions] on the street."

206. During this time, Optum and its affiliates also worked directly with the opioid manufacturers to increase opioid utilization. For example, from the early 2000s until 2015, OptumInsight, a sister company of OptumRx, also helped Purdue generate clinical studies, educational materials, and marketing programs to downplay the addictive properties of OxyContin and expand its use throughout the country.

207. In order to do so, OptumInsight was paid by Purdue to reverse engineer studies to achieve desired outcomes; create algorithms to identify potential pain patients to suggest OxyContin prescriptions; and create large-scale marketing plans to convince payors that long-term opioid usage was not only useful for many types of pain and did not lead to serious addiction for long-term opioid users.

208. For example, in 2000 and 2001, OptumInsight (then known as Ingenix) worked with Purdue to develop algorithms and studies to identify chronic pain patients. One was an algorithm that would mine UHC's claims data called "the chronic pain patient identification algorithm." The other was called "Profiling the OxyContin Patient." The purpose of this study was to assist Purdue in shifting formulary discussions with PBMs/health plans from a purely per-member fiscal discussion to an overall "clinical and fiscal" benefits discussion. Purdue paid for this study, in part, to counter the recent focus in the market on "cases of diversion" and "premium pricing" of OxyContin. Purdue's goal of this study was to use the OptumInsight's "data/evidence" to demonstrate from a payor and patient perspective the clinical/financial benefit of OxyContin given the overall costs associated with the undermanagement of pain.

209. In October 2002, OptumInsight proposed a "Chronic Pain Management" study and education initiative to present a series of teleconferences to providers in the UHG/UHC network. The purpose of this educational initiative was to "optimize patient care in the treatment

of chronic pain.” One of the themes of this report is that “[m]ost specialists in pain medicine and addiction agree that patients with prolonged opioid therapy . . . do not usually develop addictive behavior” and to convince the providers that “[o]pioids are effective, have a low addiction potential, and may have fewer long-term side effects than other pain treatments.”¹²⁷

210. This clinical initiative was launched by UHG that same year; UHG requested \$200,000 to implement the initiative and begin targeting plans for the program. Purdue stated that while that was a big investment, that the return would be high. The study with UHG proved overall to “significantly improve the relationship with this client” and would “provide outcomes data that can prove valuable in the future with regard to placement and pull-through for United and other major HMOs.”¹²⁸

211. In February 2003, UHC threatened to implement a stricter quantity limit on OxyContin and other Purdue products. Purdue worked with OptumInsight to provide “new data” for June 2003. Based on the joint efforts of Purdue and OptumInsight, UHC subsequently doubled its quantity limit (to a level that Purdue stated was high enough that it should not affect OxyContin sales).

212. In March 2005, OptumInsight prepared an Executive Summary to Purdue for “A Usual Care, Multicenter, Open-label, Randomized, 4-month Parallel Group Trial to Compare the Impact of Therapy with OxyContin on Health Outcomes and Research Utilization in Subjects with Moderate to Severe Osteoarthritis Pain of the Hip or Knee.” The purpose of the study was to present evidence to “health-system decision-makers” of the cost effectiveness of treating osteoarthritis with OxyContin. OptumInsight went on to present this study on behalf of Purdue at

¹²⁷*Id.* at page 132.

¹²⁸*Id.*

the International Society for Pharmacoeconomics and Outcomes Research annual meeting in 2005 where it won an award.

213. Because these studies were reverse-engineered and constructed in order to advance Purdue's market share of OxyContin, in certain instances, members of the medical/health care community pushed back on Purdue's and OptumInsight's joint medical journal publications. When that occurred, the two companies worked together to respond.

214. From 2011 through at least 2015, Purdue and OptumInsight worked together to build a comprehensive, multi-step "aspirational statement" and "evidence-generated" strategies for Butrans, OxyContin, Intermezzo, Targin, and hydromorphone. The goal of this coordinated effort was to identify the best way to position these drugs with the public, patients, providers, and payors to increase utilization and maximize sales.

215. The first phase occurred in April 2012. It included a "Product Review" for each Purdue drug to "complete a focused review of product, literature, and on-line information to establish the likely interplay between the product, competitors, and the market access and reimbursement environment."¹²⁹

216. The second phase occurred simultaneously in April 2012 and included "Event Mapping" which was an in-person workshop for the "Satellite [Purdue- OptumInsight] Team." The purpose of Event Mapping was to identify "significant events that will affect future evidence generation strategies."¹³⁰

217. The third phase occurred in June 2012; it was called the "Aspirational Value Proposition" phase. During this time, the group would create the "ideal value proposition

¹²⁹*Id.* at page 132.

¹³⁰ *Id.*

statement” which “is concise, appeals to payers’ strongest decision- making drivers and is evidence based to: (1) identify the burden and unmet need that OxyContin will fulfill;(2)describe the solution provided by OxyContin compared to existing treatments; (3) describe the risks of OxyContin compared to existing treatments; and (4) delineate the economic benefit of OxyContin compared to existing treatments.” OptumInsight’s OxyContin “value statement” was targeted at moderate to severe pain and to endorse the reformulated OxyContin as lowering abuse, addiction, and diversion rates.¹³¹

218. The fourth phase occurred in September 2012. It included a “Semi Structured Payer Interview Guide for Hydrocodone, Oxycontin, Butrans to gather insight re: market access and reimbursement considerations.”

219. The fifth phase, occurring in November 2012 included reviewing “Results from Payer Interviews Oxycontin, Butrans, Hydrocodone.”

220. The next month, the group started the sixth phase, called “Evidence Generation Plan for OxyContin. Recommendations for a value evidence generation plan to support aspirational value proposition evidence base.” OptumInsight relied on this evidence to revise the “Aspirational Value Proposition.” One notable change—removing the value proposition that “Abuse of prescription opioids (primary and secondary) has substantial impact on society.” The reason behind removal was “Payers value pain management. They perceive tamper resistance and abuse deterrence as societal benefits which they cannot further impact unless all products are tamper resistant.” OptumInsight’s motivation behind the “Payers value pain management” was financially motivated based on aspirational statement #1 “annual total and direct costs of

¹³¹ Id.

moderate to severe chronic pain in the US are 2- to 3-fold higher than the economic burden posed by other major conditions such as diabetes, heart disease and obesity.”¹³²

221. From 2003 to at least 2012, OptumInsight conducted similar studies for other opioid manufacturers. For example, in 2012, OptumInsight did an analysis attempting to show that Suboxone film vs. a tablet formulation was superior to prevent diversion/abuse/misuse.

222. Alongside the studies OptumInsight was producing for Purdue to further legitimize the proliferation of opioids without adequate controls throughout the United States, OptumHealth, a subsidiary of UHC, began an “educational partnership” campaign in the early 2000s to educate nurses and case managers throughout the country on the undertreatment of pain.

223. In 2004, David Rosen, an employee at Purdue, connected his father, Dr. Michael Rosen, a National Medical Director at OptumHealth from 1996-2021, with Account Executives at Purdue to begin educating the UHC and client clinical staff on how to effectively manage pain. Dr. Rosen was not only the head medical director at OptumHealth, but UHC’s Pharmacy and Therapeutics (“P&T”) Committee directly reported to him. His son was on the marketing team at Purdue and utilized his connection with his father to connect Purdue with OptumHealth and UHC.

224. In January 2005, Dr. Rosen coordinated with Purdue to present two major CE programs to be given to case managers at UHC. The next month, the educational initiatives were implemented.

225. Part of the program targeted nurse practitioners, and included a presentation

¹³²*Id* at page 134.

called “Communication to Enhance Collaboration and Outcomes.” The presentation was wholly endorsed and coordinated with Optum’s Dr. Rosen. The PowerPoint presentation emphasized the “Possible Adverse Effects of Undertreated Pain” and had speaker notes to quote during the presentation that advocated for increased opioid use and stated “[i]f we continue to provide pain care as it has always been provided, patients will continue to suffer needlessly.” The same presentation was given to case managers, then expanded to UHC affiliated groups throughout the country, including to risk managers, telephone triage nurses, and every case manager.¹³³

226. In 2006 and 2007, Dr. Rosen and Purdue worked together on multiple programs, including a program called “UHC Educate the Educator.”

227. In 2009, Dr. Rosen worked with Purdue to roll out a six month “chronic pain mgmt. program” that would directly link to Purdue’s “Partners Against Pain” website. The program would focus on case managers for Optum throughout the country and would focus on Purdue’s FACETS modules. The series would be presented by Optum Medical Directors and some Purdue employees. In March 2009, Optum employees reached out to Purdue to facilitate Medical Director Faculty Forum presentations regarding pain. One of the faculty presentations was about how to treat lower back pain with opioids using one of the FACETS topics. Optum distributed the literature for the topic to medical directors. Following this, Purdue held multiple educational seminars with the Medical Directors at Optum to then disseminate this information to hundreds of case managers throughout the country via seminars and literature.¹³⁴

228. In sum, the Manufacturing and Marketing Defendants’ efforts to disseminate misinformation about opioid addiction, opioid use for chronic pain, and opioids as a first-line

¹³³*Id* at page 135.

¹³⁴*Id* at page 136.

therapy inappropriately expanded the opioid market. And since the 1990s, the Major PBMs collaborated with Purdue to spread this misinformation in an effort to increase opioid utilization and sales. The result of these joint efforts (in Express Scripts' own words) was the "opiate explosion: vast increase in prescribing [and] more potent formulations [of opioids]." ¹³⁵

C. The Manufacturing and Marketing Defendants' Scheme Succeeded in Expanding Opioid Prescribing

229. The Manufacturing and Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. The Manufacturing and Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and MME per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, as of 2018 between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

230. The Manufacturing and Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an

¹³⁵*Id.*

epidemic of addiction and abuse.

231. Endo, for example directed the majority of its marketing budget to sales representatives, with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER's uses; virtually all of Endo's opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives. Similarly, according to an internal Janssen training document, sales representatives were told that sales calls and call intensity have high correlation to sales.

232. Teva also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Teva attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”¹³⁶ Actiq became Teva's second best-selling drug. By the end of 2006, Actiq's sales had exceeded \$500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don't have cancer.”¹³⁷

233. Each of the Manufacturing and Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of

¹³⁶Cephalon, Inc., Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

¹³⁷John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2016, 12:01am), <https://www.wsj.com/articles/SB116252463810112292>.

their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. They monitored doctors' prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs, for instance. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (*e.g.*, the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF opioids.

234. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior. The effects of sales calls on prescribers' behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

235. Manufacturing and Marketing Defendants spent millions of dollars to market the Manufacturing and Marketing Defendants' drugs to prescribers and patients and meticulously

tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain. These results are directly due to the Manufacturing and Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

236. Thus, both independent studies and Manufacturing and Marketing Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

237. These increased sales included prescriptions under circumstances, in quantities, and for durations that, but for the Manufacturing and Marketing Defendants' fraudulent misrepresentations, would not have been written.

III. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR CSA AND STATE LAW DUTIES IN ORDER TO MAXIMIZE THEIR OPIOID PROFITS

238. The Manufacturing and Marketing Defendants, the Independent Distributor Defendants, and the Pharmacy Defendants, who were registrants under the federal Controlled Substances Act ("CSA"), failed to provide the requisite controls against diversion. They shipped suspicious orders with indicia of diversion without performing the required due diligence, and/or they dispensed prescriptions with red flag indications of diversion, again without performing the due diligence required by law.

239. For over a decade, all Defendants aggressively sought to bolster their revenues, increase profits, and grow their shares of the prescription opioid market by unlawfully and surreptitiously increasing the volume of opioids they sold nationwide.

240. However, Defendants are not permitted to engage in a limitless expansion of

their market shares through the unlawful sale of highly addictive controlled substances. Rather, as described below, Defendants are subject to various duties under the federal Controlled Substances Act and state law—duties they failed to perform.

241. As detailed below, the Defendants’ failure to comply with their duties under the CSA and state law resulted in the dispensing of opioids pursuant to invalid prescriptions. And but for Defendants’ failure to carry out their CSA and state law duties, would not have been dispensed.

A. The Supply Chain Defendants Had Obligations Under the CSA and State Law to Provide Effective Controls Against Diversion

242. The CSA requires any “person” that manufactures, distributes, or dispenses controlled substances to register with the federal Drug Enforcement Administration (“DEA”). The CSA and its implementing regulations then impose specific duties on registrants to provide safeguards against the diversion of controlled substances. The CSA thus creates a “closed system” in which every participant in the supply chain for controlled substances is known, registered, and subject to regulation. Controlled substances are categorized on “schedules” according to the degree of danger they pose. Prescription opioids are controlled substances under the CSA and most of them are categorized as “Schedule II” substances, the most restrictive category of drugs that can lawfully be prescribed.

243. The Defendant entities that manufacture, distribute, and/or dispense prescription opioids are DEA registrants under the CSA and thus are required to comply with the statutory and regulatory requirements imposed on registrants.

244. The fundamental duty imposed by the CSA is the obligation to provide effective controls against diversion. *See* 21 C.F.R. § 1301.71. *Every* DEA registrant is subject to this duty.

245. The Defendant entities that manufacture, distribute, and/or dispense prescription opioids are also subject to duties under state law, which similarly require that Defendants provide effective controls against diversion.

1. CSA DUTIES OF MANUFACTURERS AND WHOLESALERDISTRIBUTORS

246. In addition to their overall duty to provide effective controls against diversion, registrants that are manufacturers or wholesale distributors (a) must design and implement a system, to identify suspicious orders; (b) report suspicious orders to the DEA; and (c) not ship suspicious orders unless and until they are able to establish, through due diligence, that they are not likely to be diverted. See 21 C.F.R. § 1301.74; see also *Masters Pharm. Inc.*, 80 Fed. Reg. 55418-01, 2015 WL 5320504 (DEA Sept. 15, 2015); *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, at *4-10 (N.D. Ohio Aug. 19, 2019); *City & County of San Francisco v. Purdue Pharma L.P.*, 620 F. Supp. 3d 936, 951-52 (N.D. Cal. 2022).

247. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Other factors that may raise suspicions may include, for example, “[o]rdering the same controlled substance from multiple distributors.” These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of

the industry.

248. Once a registrant has identified a suspicious order, it must refuse to ship that order unless and until it can establish, through due diligence, that the order is unlikely to be diverted.

249. The Federal Trade Commission (“FTC”) has recognized the unique role of distributors in the CSA controlled system. Since their inception, the Independent Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, the Independent Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, the Independent Distributor Defendants offer their pharmacy customers sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. The Independent Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. See *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC’s motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, the Independent Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

250. The Manufacturing and Marketing Defendants also have specialized and detailed

knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS Health. (Because the IMS Health data comes from the Pharmacy Defendants, the Pharmacy Defendants, too, have access to the same detailed information as the Manufacturing and Marketing Defendants.) Their extensive boots-on-the-ground activity through their sales force allows Manufacturing and Marketing Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturing and Marketing Defendants regularly mined data, including chargeback data, which allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, which would have alerted them, independent of their sales representatives, to suspicious prescribing. This information gave Manufacturing and Marketing Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in preventing diversion and fulfilling their obligations under the CSA.

251. Manufacturing and Marketing Defendants and Distributor Defendants have a duty, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

252. As described below, the Manufacturing and Marketing Defendants and Distributor Defendants breached these duties by failing to: (a) provide effective controls against diversion; (b) design and implement appropriate systems to identify suspicious orders; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

2. CSA DUTIES OF DISPENSERS

253. In addition to their overall duty to provide effective controls against diversion, registrants that dispense opioids are prohibited from filling prescriptions that are not written for a legitimate medical purpose. *See* 21 C.F.R. § 1306.04(a); *see also In re Nat'l Prescription Opiate Litig.*, 589 F. Supp. 3d 739, 784-85 (N.D. Ohio 2022) (quoting jury instruction that described CSA duties of dispensers); *City & County of San Francisco v. Purdue Pharma L.P.*, 620 F. Supp. 3d 936, 958-59 (N.D. Cal. 2022). Dispensers must review prescriptions for red flags, perform due diligence on prescriptions that raise red flags, and refuse to fill prescriptions for which red flags cannot be resolved. Not only the pharmacists at the dispensing counter, but the pharmacy itself and its corporate parents, are required to ensure that only valid prescriptions are filled.

254. DEA has identified several types of “unresolvable red flags” that, when present in a prescription, must prevent the prescription from being filled by the overseeing pharmacist. These unresolvable red flags include: a prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; multiple prescriptions issued by the same practitioner to patients from the same address, prescribing the same controlled substances in each prescription; a high volume of patients presenting prescriptions and paying with cash; and a prescription presented by a customer who has traveled significant and unreasonable distances from their home to see a prescriber and/or to fill the prescription at the pharmacy.

255. DEA guidance also instructs pharmacies to monitor for red flags that include: (1) prescriptions written by a prescriber who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances as compared to other practitioners in the area, and (2) prescriptions for antagonistic drugs, such as depressants and stimulants, taken at the

same time as opioids. Most of the time, these attributes are not difficult to detect and should be easily recognizable by the Pharmacy Defendants' diversion-control systems.

256. The DEA has also explained these red flags in individual meetings with the Pharmacy Defendants. For example, in December 2010, DEA hosted a meeting with CVS's representatives and counsel and advised CVS of the "red flags . . . that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose."¹³⁸

257. Examples of red flags that the DEA identified during its meeting with CVS include:

- a. many customers receiving the same combination of prescriptions (*i.e.*, oxycodone and alprazolam);
- b. many customers receiving the same strength of controlled substances (*i.e.*, 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam);
- c. many customers paying cash for their prescriptions;
- d. many customers with the same diagnosis codes written on their prescriptions (*i.e.*, back pain, lower lumbar, neck pain, or knee pain); and
- e. individuals driving long distances to visit physicians and/or to fill prescriptions.¹³⁹

258. In a 2016 presentation to the American Pharmacists Association, the DEA

¹³⁸Declaration of J. Rannazzisi in *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp.2d 145 (D.D.C. 2012).

¹³⁹*Id.*

reiterated that retail pharmacies must watch for red flags such as large numbers of customers who receive the same combination of prescriptions, receive the same strength of controlled substance prescription (often for the strongest dose), have prescriptions from the same prescriber, and have the same diagnosis code.

259. Many of these red flags are acknowledged in a “Stakeholders” memorandum created by many of the Pharmacy Defendants, including CVS and Walgreens, and others in the business of selling controlled substances for profit, like Purdue, Express Scripts, Cardinal, and their trade organizations, including the Healthcare Distribution Management Association (“HDMA”) (now known as the Healthcare Distribution Alliance (“HDA”), the National Association of Chain Drug Stores (“NACDS”), and the Pharmaceutical Care Management Association (“PCMA”).

260. In the context of bellwether cases brought by governmental plaintiffs, the MDL Court held that “both pharmacists and pharmacies bear all the obligations imposed [by the CSA] upon practitioners and dispensers.” CT3 MTD Order, Doc. No. 3403 (Aug. 6, 2020). The Court further held that, in light of the data that pharmacies are required, by law, to collect, they must make use of that data to provide effective controls against diversion. *Id.* As the Court explained:

261. [A] pharmacy is required to: (1) collect and maintain specific records and data regarding its dispensing activity; (2) employ a properly licensed pharmacist; and (3) properly dispense controlled substances and avoid diversion. Therefore, both the pharmacy and the pharmacist must cooperatively identify and resolve “red flags” prior to dispensing controlled substances. The Court concludes these requirements collectively mean that the Pharmacy Defendants cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then do nothing

with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled. Possessing, yet doing nothing with, information about possible diversion would actually *facilitate* diversion, and thus violate the CSA's fundamental mandate that “*All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.*” 21 C.F.R. §1301.71(a).*Id.* at 25 (emphasis by the Court).

262. Similarly, in a case remanded from the MDL, Judge Charles Breyer of the United States District Court for the Northern District of California held that the CSA “requires pharmacists and pharmacies to identify and resolve objective signs ‘arising during the presentation of a prescription’ that create ‘a reasonable suspicion that the prescription is not, on its face, legitimate.’” No. 18-cv-07591, ECF No. 1578, at 97 (N.D. Cal. Aug. 10, 2022). Judge Breyer further held that the elements of a CSA violation in this context are that “(1) a pharmacy dispensed a controlled substance, (2) “a red flag was or should have been recognized at or before the time the controlled substance was dispensed,” and (3) “the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance.” The Court further noted that “Prescriptions with unresolved red flags cannot be dispensed.” *Id.* at 98.

B. Manufacturing and Marketing Defendants and Independent Distributor Defendants Deliberately Disregarded Their CSA Obligations Regarding Suspicious Orders to Maximize Their Opioid Profits

22. The Healthcare Distribution Management Association (“HDMA,” now known as the Healthcare Distribution Alliance (“HDA”), and prior to 2000, known as the National Wholesale Druggists’ Association (“NWDA”)), is a national trade association of pharmaceutical distributors to which the Independent Distributor Defendants belong, has long taken the position

that distributors have responsibilities to “prevent diversion of controlled prescription drugs” not only because they have statutory and regulatory obligations do so, but “as responsible members of society.” Guidelines established by the HDA also explain that distributors “[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”

23. In 2007 and 2008, the HDA began developing “Industry Compliance Guidelines” (“ICG”) that aimed to outline certain “best practices” for distributors of controlled substances. As part of its development of the ICG, the HDA met with the DEA on at least three occasions. The HDA also sought extensive input from its membership, as well as other groups such as the Pain Care Forum (“PCF”). Internal discussions concerning the ICG further demonstrate the industry’s knowledge of what was expected of them. For example, when deciding whether or not the guidelines should permit a distributor to still ship a part of an order identified as suspicious, the HDA noted that one potential downside of this approach was that “DEA correspondence/interpretation do not support this practice.”¹⁴⁰

24. The HDA released the ICG in 2008 and, in doing so, it emphasized that distributors were “[a]t the center of a sophisticated supply chain” and “uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”¹⁴¹

25. In 2016, in the appeal that arose from DEA’s enforcement action against wholesaler Masters Pharmaceuticals, Inc. for its distribution of opioids, the HDA and NACDS

¹⁴⁰1:17-md-2804, [Doc. 5716]. *Id.* at page 171.

¹⁴¹ Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x Bat1).

submitted a joint amicus brief regarding the legal duty of distributors that acknowledged that “HDMA and NACDS members” had a duty to prevent diversion. *See Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (D.C. Cir. April 4, 2016). As described below, both the HDA and NACDS have both long taken the position that distributors have responsibilities to “prevent diversion of controlled prescription drugs” not only because they have statutory and regulatory obligations do so, but “as responsible members of society.”

26. In addition, the DEA, for example, in April 1987, sponsored a three-day “Controlled Substances Manufacturers and Wholesalers Seminar” that was attended by “over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers.”¹⁴² According to the executive summary of the event, Ronald Buzzeo held a session on “excessive order monitoring programs,” wherein he explained:

[A]ny system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program.” Another area at issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.

27. Specifically, in August 2005, the DEA’s Office of Diversion Control launched the “Distributor Initiative.” The Distributor Initiative did not impose any new duties on distributors, but simply reminded them of their duties under existing law. The stated purpose of the program was to “[e]ducate and inform distributors/manufacturers of their due diligence

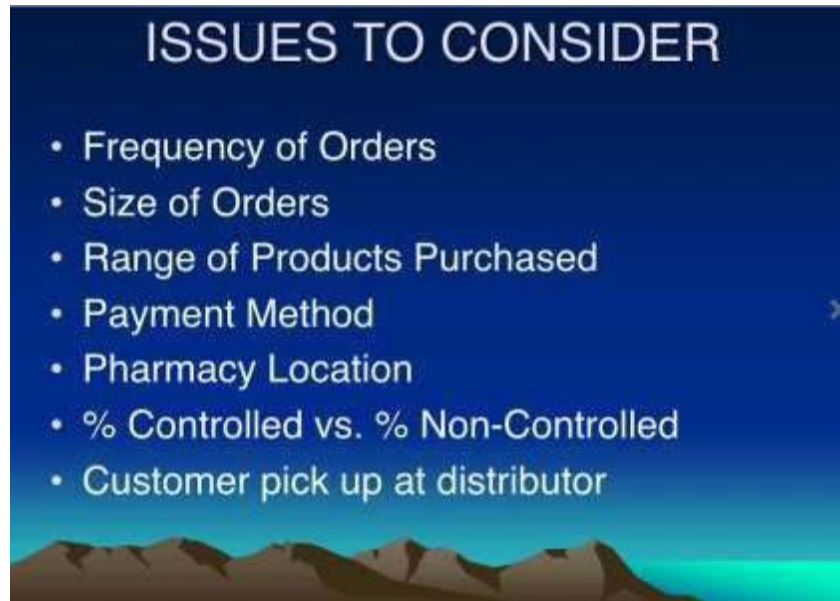
¹⁴²1:17-md-2804, [Doc. 5716]. *Id.* at page 172.

responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their [Automation of Reports and Consolidated Orders System (“ARCOS”)] data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances.”¹⁴³ The CSA requires that distributors (and manufacturers) report all transactions involving controlled substances to the United States Attorney General. This data is captured in ARCOS, the “automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions,”¹⁴⁴ described above, from which certain data was recently made public.

28. As part of the Distributor Initiative, the DEA gave several presentations to distributors both individually and through presentations and discussions at Defendants’ trade groups meetings directly targeted at some of the red flags of diversion that the Defendants were obligated to consider and monitor as part of their requirements under the law.

¹⁴³ Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013), https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

¹⁴⁴ U.S. Dept. of Justice, Drug Diversion Administration, Diversion Control Division website, <https://www.deadiversion.usdoj.gov/arcos/index.html>.



29. The DEA has hosted many different conferences throughout the years, including Pharmacy Diversion Awareness Conferences, to provide registrants with updated information about diversion trends and their regulatory obligations. The DEA also frequently presented at various other conferences for registrants at the national, state, or local level.

30. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. As an example, the DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances."¹⁴⁵

31. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances. The 2006 letter

¹⁴⁵ U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration available at https://www.dea diversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

emphasized that distributors are:

one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.¹⁴⁶

32. The letter also warned that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

33. The DEA sent a second letter to distributors on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they must each abide by statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”¹⁴⁷

34. The DEA’s December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”

35. In September 2007, the NACDS, among others, also attended a DEA conference

¹⁴⁶ Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Off. of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (“2006 Rannazzisi Letter”); *see also* CVS-MDLT1000091513; WAGMDL00757797.

¹⁴⁷ Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (“2007 Rannazzisi Letter”).

at which the DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders. Walgreens, specifically, registered for the conference.

36. The DEA's regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as Defendants were well aware of their legal obligations. There is a long history of enforcement actions against registrants for their compliance failures. For example, in 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against three of Cardinal Health's distribution centers and on December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York. Similarly, on May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement with the DEA related to its failures in maintaining an adequate compliance program. Subsequently, in January 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, inter alia, failure to identify and report suspicious orders at several of its facilities.

IV. AMERISOURCEBERGEN DISTRIBUTED PRESCRIPTION OPIOIDS IN VIOLATION OF ITS CSADUTIES

37. AmerisourceBergen's ("ABDC") Suspicious Order Monitoring System ("SOMS") failed to adhere to even the most basic requirements of the CSA. For instance, prior to 2007, AmerisourceBergen's SOMS policies only attempted to identify "excessive" orders that exceeded a particular threshold, rather than "suspicious" orders of unusual size, pattern, or frequency, as is required by the CSA. At that time, AmerisourceBergen had no meaningful due diligence process in place to investigate whether such "excessive" orders otherwise qualified as "suspicious," other than to confirm a customer was licensed with the state and registered with the

DEA. In fact, up until 2007, AmerisourceBergen's official national policy was to ship all orders of opioids it received, regardless of size, frequency, deviations from prior orders, deviations from averages, deviations from defined thresholds, or even whether that order was deemed "suspicious."

38. In 2007, the DEA initiated an Enforcement Action against AmerisourceBergen which resulted in the suspension of its Orlando Distribution Center, due to its improper filling and shipment of suspicious opioid orders. To obtain authorization to re-open the facility, AmerisourceBergen was forced to update its diversion control program, including adding (1) amore in-depth due diligence process, and (2) a requirement to stop shipping suspicious orders to customers.

39. After the 2007 Enforcement Action, ABDC implemented a "Know Your Customer" due diligence policy which was effectuated through the Form 590 retail pharmacy questionnaire. The Form 590 process was flawed in that it exempted existing customers and retail chain pharmacies from the form requirements. Moreover, a vast number of the forms that ABDC did collected were either illegibly filled out or contained substantial omissions. Against this backdrop, AmerisourceBergen implemented a "CSRA 590 Validation Project," which revealed that it had only received about 10% of the required documents it sought from its customers.

40. In 2015, ABDC engaged an outside consultant, FTI Consulting Inc. ("FTI") to review its SOMS. FTI issued a damning report documenting the findings of its audit of ABDC's compliance activities. The FTI report disclosed a litany of problems, including a lack of resources, a lack of formal training, crushing administrative demands, inconsistent policies and communication break-downs. In addition to the report, FTI highlighted its concerns with

AmerisourceBergen's regulatory compliance obligations relating to diversion control in a forty-five page chart discussing FTI's findings. ABDC took no action and made no changes to its diversion policies or procedures in response to these alarming findings.

41. AmerisourceBergen's SOMs deficiencies had real consequences in the communities in which AmerisourceBergen does business. For example, a DEA Suspension Order concerning one of AmerisourceBergen's Ohio customers, East Main Street Pharmacy, documented deaths that occurred as a result of a failure to prevent diversion. Julie Fuller, an AmerisourceBergen sales representative who was responsible for East Main Street Pharmacy, testified in the suspension proceedings. Notwithstanding the obvious signs of illegal activity occurring at the East Main Street Pharmacy, including the fact that more than half of the pharmacy's prescriptions were written by an out-of-area doctor prescribing high volumes of controlled substances, Ms. Fuller "acknowledged that the purpose of her visits was not 'to observe [the pharmacist]' in the practice of pharmacy but to get his business." Ms. Fuller also stated that as an account manager, AmerisourceBergen only provided her general sales training, and did not provide any training or information on (a) how to identify questionable pharmacy behavior like suspicious dispensing, sales, or prescription filling practices, (b) how to report concerns regarding those behaviors, or (c) how to ensure that account managers only signed up and maintained accounts with legitimate pharmacies

42. Despite a reported shift in its due diligence policies after the 2007 settlement with the DEA, AmerisourceBergen's order monitoring program was a failure both in its implementation and its ability to adequately prevent diversion.

2. CARDINAL HEALTH DISTRIBUTED PRESCRIPTION OPIOIDS IN VIOLATION OF ITS CSADUTIES

43. Cardinal Health has admitted that it failed to comply with the requirements of

the CSA. In a May 2012 agreement with the DEA, Cardinal stated that it “admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate.” Cardinal also failed to meet its duties to maintain effective controls under the CSA prior to January 2008. In the 18 months prior, Cardinal had accumulated nearly \$1 billion in fines, settlements, and lost business as a result of multiple regulatory actions, including the suspension of Cardinal’s distribution centers’ licenses for failure to maintain effective controls against the diversion of opioids.

44. In late 2007 and early 2008 the DEA served immediate suspension orders or orders to show cause on four Cardinal distribution centers in Washington, Texas, Florida, and New Jersey for distributing opioids to pharmacies Cardinal knew, or should have known, were diverting opioids. This action by the DEA resulted in a Settlement and Release Agreement and Memorandum of Agreement that covered the “alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, *at all distribution facilities. . . operated, owned, or controlled by it.*”

45. The DEA’s 2008 action was in direct response to the fact that Cardinal did not have a suspicious order monitoring system in place that would allow it to sufficiently detect and report suspicious orders of opioids. Specifically, Cardinal did not have a specific protocol to monitor possible drug diversion (outside of ARCOS) activity with internet pharmacies or wholesaler accounts. Cardinal simply did not monitor what these accounts purchased.

46. Cardinal’s own counsel admitted in 2008 that Cardinal “does not yet have a system for detecting all suspicious orders.” Prior to 2008, Cardinal primarily reported suspicious orders to the DEA in the form of monthly summaries called Ingredient Limit Reports (“ILR”) *after they had already been shipped.* In a company of over 30,000 employees, Cardinal tasked

just three employees with reviewing the ILRs for the entire country.

47. In 2007, Cegedim Dendrite was hired to conduct an audit of Cardinal's SOMS. The audit concluded, among other things, that because the ILRs were based on historical information they were not sufficient to monitor deviations in ordering patterns on a real time basis and did not substitute for real time automated analysis of pattern and frequency.

48. By its own admission, Cardinal did not have a policy to stop shipment of suspicious orders until 2008. Internal Cardinal documents indicate that nationwide, Cardinal reported only a few dozen suspicious orders from 2008-2013.

49. As an additional indication of its failure to maintain effective controls against diversion, Cardinal provided preferential treatment to chain pharmacies, treating them differently than retail independent pharmacies with respect to setting thresholds and conducting due diligence. Cardinal refused to impose the same requirements on chain customers that it did on retail independents because, as stated in Cardinal's June 27, 2006 letter, large national pharmacy chains can "take their billions upon billions of dollars in business to any wholesaler in the country."

50. Cardinal failed to conduct due diligence on its retail pharmacy chain customers and instead relied on the chains' inhouse loss prevention departments to report this information. However, Cardinal did not make any effort to evaluate chain pharmacies anti-diversion programs.

51. In 2012, the DEA began another prosecution of Cardinal for failing to prevent diversion and for not complying with the 2008 MOA. As a result, the DEA served another Immediate Suspension Order on Cardinal's distribution facility in Lakeland, Florida (also one of the facilities at issue in the 2008 action) for distributing excessive amounts of oxycodone to retail

pharmacies, including some chain pharmacy stores.

52. In response to the 2012 investigation, Cardinal admitted that it failed to comply with the 2008 MOA and had not engaged in proper due diligence in evaluating its customers for diversion. Complying with the CSA was simply not a priority at Cardinal Health.

3. MCKESSON DISTRIBUTED PRESCRIPTION OPIOIDS IN VIOLATION OF ITS CSA DUTIES

53. McKesson's systemic failure to follow the CSA requirements has been documented in two large settlements with the DEA. In the January 2017 settlement with the DEA, McKesson accepted responsibility for violating the CSA and expressly acknowledged that:

at various times during the period of January 1, 2009, up through and including the Effective Date of this Agreement (the "Covered Time Period") it did not identify or report to the DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 8942(a)(5).

54. From at least 1997 until May 2007, the sole system utilized by McKesson to identify and report suspicious orders of controlled substances was found in Section 55 of the McKesson Drug Operations Manual. McKesson's "Section 55" Program was a rudimentary system that failed to meet the most basic CSA requirements. McKesson's own regulatory employees have acknowledged that this system did not flag true suspicious orders as required by the CSA.

55. McKesson's Section 55 Program was also flawed in that it did not include a requirement to block orders that were deemed "excessive" and ultimately reported to the DEA. In fact, McKesson made no effort to block suspicious orders until it began utilizing the Controlled Substance Monitoring Program in May 2008. McKesson did not attempt to investigate the legitimacy of excessive orders under the Section 55 program either.

56. The shortcomings of Section 55 are best illustrated in DEA's investigation into

large shipments of opioids provided by McKesson to rogue internet pharmacies in 2005 and 2006. In January of 2006, DEA notified McKesson that it had identified more than 2 million doses of hydrocodone delivered by McKesson to several rogue internet pharmacies during a three-week period. McKesson conceded that these extremely large orders were not flagged under its Section 55 system, in part, because McKesson did not track the sale of generic drugs for suspicious order monitoring purposes under that system.

57. In May 2007, McKesson launched its Lifestyle Drug Monitoring Program (“LDMP”) but it was short-lived and did little to improve upon Section 55’s shortcomings. LDMP was a threshold system that was limited to four drugs (oxycodone, hydrocodone, alprazolam and phentermine). The system triggered once a customer ordered above an 8000 dosage unit threshold in a given month. However, the LDMP had no mechanism by which to block orders once the 8,000 unit threshold was met and while investigations were ongoing. In fact, pharmacy customers were routinely permitted to exceed the 8,000 monthly dosage thresholds prior to a due diligence review being completed by McKesson.

58. On May 2, 2008, McKesson entered into a settlement agreement with the DEA and DOJ and paid \$13,250,000 in fines for numerous violations of the CSA concerning the distribution of opioids.

59. Even with the adoption of its new Controlled Substances Monitoring Program (“CSMP”) in 2008, McKesson still failed to identify and report suspicious orders. The CSMP continued to apply monthly thresholds, but unlike the LDM, the CSMP’s monthly thresholds applied to all opioid products. However, thresholds could be adjusted pursuant to a threshold change request and the records are devoid of evidence of anything resembling adequate due diligence. The CSMP was also the first time that McKesson established a process for blocking

opioids orders that were identified as suspicious. Not surprisingly, CSMP contained multiple loopholes to ensure as few orders as possible were blocked, ensuring that the controls that were put into place remained completely ineffective.

60. Although McKesson established thresholds under the CSMP, those thresholds were frequently set far too high ever to be triggered and McKesson routinely increased thresholds without obtaining adequate justification for the increase. Like Cardinal, McKesson displayed a pattern of absolute deference to retail national account customers when it came to threshold increases. Moreover, McKesson took affirmative steps to reduce the number of blocked controlled substance orders by warning customers that they were approaching a threshold. This process ensured that customers could seek an increase before McKesson would be forced to block their orders.

61. It was not until November of 2013 that McKesson, acknowledging the impropriety of providing these warning reports to customers, implemented a new policy prohibiting the communication of specific thresholds or providing threshold warning reports.

62. While the CSMP could have been used as a tool to identify suspicious orders and properly investigate them, significant efforts were undertaken by McKesson to thwart the effectiveness of the system as a whole.

63. Ultimately, DEA and DOJ concluded that McKesson's desire for increased sales and customer retention had overridden its obligations to report suspicious orders and jeopardized the health and safety of people around the country. DEA and DOJ described McKesson's due diligence failures as to opioids as both "nationwide" and "systemic." As a result of these broad sweeping due diligence failures, McKesson agreed to a \$150,000,000 settlement with the DEA and DOJ.

64. Additionally, as noted above, McKesson accepted responsibility for its nationwide due diligence failures as to opioid distribution spanning 2009-2017 and acknowledged that it had not fulfilled its obligation under the CSA during this period. McKesson itself, through its corporate designee, Nate Hartle, has testified that as a result of its conduct McKesson accepts partial responsibility for the society costs of the opioid epidemic today.

C. The Pharmacy Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls Against Diversion in Both Their Distribution and Their Dispensing of Controlled Substances

1. THE PHARMACY DEFENDANTS WERE ON NOTICE OF THEIR CSA OBLIGATIONS AND OF THE FACT THAT OPIOIDS WERE BEING DISPENSED WITHOUT LEGITIMATE PRESCRIPTIONS

263. The Pharmacy Defendants are members of the National Association of Chain Drug Stores (“NACDS”), a trade association advancing the interests of pharmacies. NACDS has partnered with HDA; the two groups viewed their relationship as a strategic “alliance.” CVS also has been an “allied” member of the HDMA.

264. In 2006, the NACDS issued a “Model Compliance Manual” intended to “assist NACDS members” in developing their own compliance programs. The Model Compliance Manual notes that a retail pharmacy may:

“[G]enerate and review reports for its own purposes” and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:

- Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.
- Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.
- Geographic Zip Reports, which identify possible “doctor shopping” schemes or “script

mills” by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

265. Each of the Pharmacy Defendants does substantial business throughout the United States. This business includes the dispensing of prescription opioids and has, at times, also involved the distribution of prescription opioids.

266. Statewide ARCOS data confirms that the Pharmacy Defendants distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in the communities where Plaintiffs practiced or continued to practice and provided emergency medical services.

267. The Pharmacy Defendants developed and maintained extensive data on opioids they distributed and dispensed. Through this data, they had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and specifically in the communities where Plaintiffs provided emergency medical services. They used the data to evaluate their own sales activities and workforce. The Pharmacy Defendants also provided data regarding, *inter alia*, individual doctors to drug companies, which targeted those prescribers with their marketing, in exchange for rebates or other forms of consideration. The Pharmacy Defendants’ data is a valuable resource that they could and should have used to prevent them from dispensing invalid prescriptions, but, as described in detail below, they failed to do so.

268. Performance metrics and prescription quotas adopted by the Pharmacy Defendants for their retail stores contributed to their failure. Under CVS’s Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or

customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year.

269. This problem was compounded by the Pharmacy Defendants' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

270. The Pharmacy Defendants also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of invalid prescriptions.

271. The Pharmacy Defendants failed to analyze some or all of the following: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

272. The Pharmacy Defendants also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

273. The Pharmacy Defendants also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

274. The Pharmacy Defendants were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. ALL PHARMACY DEFENDANTS DISTRIBUTED AND DISPENSED PRESCRIPTION OPIOIDS IN VIOLATION OF THEIR CSADUTIES

275. The Pharmacy Defendants failed to fulfill their legal duties and instead routinely distributed and/or dispensed controlled substances while ignoring red flags of diversion and abuse. Upon information and belief, the allegations detailed below regarding CVS, Walgreens, and Walmart's failures violations of their CSA Duties similarly apply to all Pharmacy Defendants.

A. CVS

276. CVS operates a number of pharmacies in South Carolina, Missouri and throughout the United States and has, at times, also acted as a wholesale distributor supplying opioids to those stores. CVS failed to comply with its CSA duties as a distributor to monitor for and refuse to ship suspicious orders, and it failed to comply with its CSA duties as a dispenser to ensure that it only dispensed legitimate opioid prescriptions. This conduct by CVS resulted in excessive and unreasonable amounts of opioids shipped to and dispensed in South Carolina, Missouri and throughout the United States, and caused Plaintiffs' damages.

a. Cvs Failed To Maintain An Effective Suspicious Order Monitoring System Or To Complete Necessary Due diligence.

277. CVS distribution centers, in tandem with outside wholesalers, such as Cardinal, supplied opioids to CVS pharmacy stores until October 2014. CVS self-distributed hydrocodone and hydrocodone combination products to its own stores, of which CVS had approximately 6,000 by 2006 and 9,700 by 2014. Hydrocodone (HCP) was previously a Schedule 3 opioid, but rescheduled to FDA Schedule II status October 6, 2014. CVS ceased self-distributing hydrocodone the same day the rescheduling took effect.

278. CVS pharmacies nationwide placed orders with CVS distribution centers through CVS's central mainframe computer ordering system.

279. Before 2009, CVS, which stocked and sold opioids at more than 9,000 stores across the country, lacked any meaningful system for suspicious order monitoring ("SOM"). Instead, CVS relied on the gut instincts of pickers and packers of the drugs in the distribution center -- workers responsible for pulling items off distribution shelves for delivery to pharmacy stores -- to identify "really big" orders that they believed were simply too large.

280. Moreover, CVS lacked a training program to train its pickers and packers how to identify unusual orders of size, frequency, or pattern. CVS also did not have any written policies, procedures, or protocols with respect to the pickers' and packers' obligations until August 2013. And, there were no formal job requirements to be employed as a picker and packer.

281. In 2007, with the help of an outside consultant, CVS began work on a Standard Operating Procedure Manual ("SOP") that was intended to cover all facets of DEA controlled substances compliance, including suspicious order monitoring. However, by the summer of 2010, neither the final manual nor the SOM section was complete: Internal documents from that time acknowledge that CVS was "still in the process of writing the suspicious order monitoring

section of this standard operating procedure.” In fact, the section of the Standard Operating procedures for Suspicious Order Monitoring stated: “**BEING DEVELOPED AND WRITTEN.**” It was not completed until August of 2010. Even then, however, CVS did not have a compliant SOMs system.

282. Although CVS in theory had a “CVS DEA compliance coordinator,” the title was a sham and did not reflect actual responsibility for compliance. A CVS employee who held the position from 2008 to 2014 said that her title was only “for reference in SOPs,” not her real job. For “personnel purposes,” she was never considered the CVS DEA compliance coordinator. Moreover, she had nothing to do with suspicious order monitoring, other than “updating the SOP with what was provided for the program.”¹⁴⁸

283. It was only in 2009 that CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. The automated program was delivered by an outside vendor to CVS in December of 2008.

284. CVS called the output of the flagged orders an Item Review Report (“IRR”).

285. The SOM algorithm delivered in December 2008 was designed to “pend” (or identify) an order with a score of 0.15 or higher as potentially suspicious. The higher the score the more likely the order was potentially suspicious. In July 2009 CVS reported to the algorithm designer that the SOM model was pending a large number of orders that CVS believed were “not suspicious on their face” and it requested that the model be changed. As a result, revised coefficients for the algorithm were delivered to CVS on August 27, 2009, but the pend score of 0.15 remained the same. Between June 2010 and August 2010, CVS adjusted the IRR pend score

¹⁴⁸1:17-md-2804, [Doc. 5716]. *Id.* at page 189.

from 0.15 to 0.65. The higher the score, the less sensitive the model, flagging fewer potentially suspicious orders for investigation. On February 8, 2011 a completely retuned SOM algorithm with another set of co-efficients was again delivered to CVS by the algorithm designer. The February 2011 changes returned the pend score to 0.15. CVS again changed the pend score to 0.65.

286. CVS's IRR system was deficient and failed in many respects to meet CVS's obligations as a distributor.

287. CVS also learned in 2010 that its SOM algorithm was not working properly because it monitored by drug, not active ingredient, meaning that changes in a drug's description or name caused historical data to be lost. Thus, the system was unable to determine that orders for these drugs exceeded or diverged from prior volumes or patterns.

288. CVS's SOM algorithm also failed to consider outside vendors orders. In other words, CVS's SOM system would not track how many opioids CVS was ordering from third-party distributors such as Cardinal when evaluating whether to distribute opioids to one of its pharmacies. CVS knew this was a problem, as a "[s]tore may order a little from both the OV [outside vendor] and DC [CVS distribution center] to stay under the radar." It also knew that excluding outside vendor data meant CVS "may ship a potentially reportable suspicious order from [its] DC." Stores, including one that had a "68,000 hydrocodone pill loss," could also place telephone orders to outside vendors, into which there was "no visibility . . . until a later time." This deficiency is particularly glaring because, at a corporate level, CVS had full access to the orders its pharmacies placed to outside vendors.

289. Acknowledging the ineffectiveness and deficiencies within its SOM system, CVS hired new consultants in 2012 to troubleshoot its existing SOM system for the purpose of

either fixing the deficient system or developing a new SOM system so as to attempt to become compliant with the law.

290. Still, as late as July 2013, internal e-mail reflects that CVS's primary tool for investigating suspicious orders relied on data that was months or even years old and made any analysis, "for the most part, irrelevant and pointless."¹⁴⁹

291. Not until mid to late 2014 did CVS fully implement a new SOM system. Even then, CVS encountered problems in evaluating suspicious orders for opioids and its SOM was entirely lacking. A risk analysis of the new system was conducted in June of 2014. The risk level was determined to be high for the SOM system in the following categories covering seemingly every aspect of its operation: inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; inconsistency in documenting due diligence investigations of suspicious orders; lack of engagement by the Management Team; lack of communication between the SOM Management Team and SOM Analysts; lack of resources to handle the rollout of the new SOM system to all distribution centers; and lack of clarity in how the new SOM system is identifying suspicious orders. Essentially, the new system lacked the key components of a compliant and effective SOMs system. That same year, CVS stopped distributing opioids to its retail pharmacies.

292. Meanwhile, on August 5, 2013, the DEA began another audit and investigation of the CVS distribution center in Indiana. CVS's own documents acknowledge that the DEA's investigation was focused on its failure to maintain a SOM program for controlled substances.

293. In response to queries from the DEA, CVS wrote a letter to the DEA revealing

¹⁴⁹1:17-md-2804, [Doc. 5716]. *Id.* at page 191.

that it had only stopped seven suspicious orders across the entire country. Right before sending the letter the author, Mark Nicastro, head of the CVS distribution center in Indiana, conceded internally that “I wish I had more stopped orders that went back further.” During that audit, neither Mr. Nicastro nor CVS’s Sr. Manager for Logistics, Quality, and Compliance were able to locate the final version of the SOP for the SOM program.

294. The DEA issued its closing letter on its investigation, concluding that CVS failed to design and maintain a system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Title 21 United States Code (USC) § 821, Title 21 USC § 823()(1), and Title 21 Code of Federal Regulations (CFR) § 1301.74(b) in violation of Title 21 USC §842(a)(5).

295. All orders that appeared on the IRR required a thorough due diligence investigation, but only a very small percentage were subjected to appropriate due diligence. At select times in 2013, CVS had only one full-time employee in the position of “SOM analyst” reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would identify orders as potentially suspicious based on a number of factors and “pend” the order. Even though the orders had been identified as potentially suspicious, the CVS SOM analysts would conduct an “in depth” dive on only select orders. In fact, while the SOM program could identify as many as 1,000 suspicious orders a day; the CVS employee would only do a “deep dive” on one to six orders per day.

296. Even as late as 2012 CVS’s SOMS was clearly little more than window dressing.

297. As of November 21, 2013, CVS had only reported seven suspicious orders to the DEA across all of its distribution centers and pharmacies in the United States. The first suspicious order CVS ever reported was on February 29, 2012.

b. CVS Conspired with Cardinal and McKesson to Prevent Suspicious Order Monitoring of Its Retail Pharmacies.

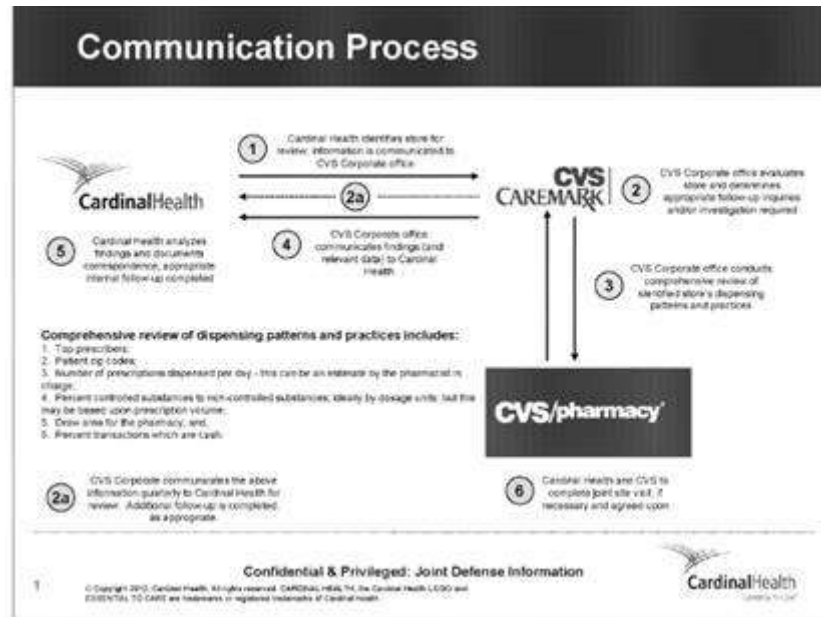
298. CVS's collaboration with distributors went from lobbying to actually preventing adequate due diligence investigations of suspicious opioid orders. CVS knows that Cardinal and McKesson have independent due diligence obligations under the CSA to monitor all sales of controlled substances for orders which deviate in size, pattern or frequency. CVS understood that, to do so effectively, Cardinal and McKesson would require access to its dispensing information. CVS did not provide dispensing information to Cardinal or McKesson. In an email from Paul Farley to Michael Mone, both Cardinal employees, Farley wrote, "I spoke with Brian Whalen at CVS a couple of times this morning... They will not provide the doctor or patient information you requested unless it is requested by the DEA. He was quite adamant about this."¹⁵⁰ CVS prevented Cardinal and McKesson from obtaining access to critical dispensing information for its pharmacies to enable Cardinal and McKesson to conduct adequate due diligence of its pharmacies. Prior to 2013, Cardinal and McKesson did not investigate CVS by calling its pharmacists or visiting CVS stores as they did with other pharmacies. Instead, distributors were instructed to contact CVS's loss prevention offices at corporate headquarters to inquire about suspicious orders, ensuring that any investigation into CVS ordering of opioids was conducted by CVS alone.

299. As a result, CVS controlled all "due diligence investigations" of its opioid orders.

300. This chart produced by Cardinal depicts the due diligence "investigations" of

¹⁵⁰1:17-md-2804, [Doc. 5716]. *Id* at page 193.

CVS orders:



301. CVS also prevented its distributors from independently determining the appropriate order thresholds for opioids at CVS stores. CVS contractually protected its right to establish and change its threshold requirement for Schedule II controlled substances with Cardinal. The agreement expressly states that CVS has the discretion under the contract to set its threshold quantities for controlled substances at any level CVS deems appropriate:

CVS requires the ability to adjust (up or down) the quantity of product our stores receive, this adjustment will be made on an NDC by NDC basis and will include a Threshold Quantity and an Adjustment Percentage. **Both the Threshold Quantity and Adjustment Percentage can be set to any value CVS deems appropriate.**¹⁵¹

c. CVS Acquired Omnicare Knowing of Systemic Failures to Control Against Diversion, But Instead of Reform, Continued Business As Usual.

302. In 2015, CVS Health Corp. acquired Omnicare, which provides pharmacy-related services to long-term care facilities and other health care facilities throughout the United

¹⁵¹1:17-md-2804, [Doc. 5716]. *Id.* at page 194.

States. Omnicare dispenses controlled substances under Certificates of Registration issued by the DEA.

303. When CVS acquired Omnicare, CVS was fully aware the DEA had previously investigated Omnicare for “alleged errors and deficiencies in paperwork requirements for controlled-substances dispensing at several of the company’s pharmacies in Ohio.”¹⁵² Omnicare publicly acknowledged the DEA’s Ohio investigation in its 2010 SEC filings, which Omnicare later settled in 2012. CVS was also aware the DEA had previously investigated Omnicare in 2007 for countrywide violations of the CSA that also led to a settlement with the DEA. In Ohio, the DEA determined that between 2007 and 2012 Omnicare:

- a. dispensed controlled substances to residents of long-term care facilities without valid prescriptions, including but not limited to dispensing controlled substances pursuant to written orders that did not contain all of the elements of a valid prescription including the signature of the prescribing practitioner, in violation of 21 U.S.C. §§ 353(b), 829 and 842(a)(1) and 21 C.F.R. §§ 1306.11 and 1306.21;
- b. failed to comply with all of the elements of the emergency oral prescription requirements set forth in 21 C.F.R. § 1306.11(d), including but not limited to dispensing Schedule II controlled substances or authorizing facility staff to remove Schedule II controlled substances from emergency supplies located at long-term care facilities without oral authorizations directly from prescribing practitioners and failing to notify

¹⁵²“Omnicare Faces Federal Probe, Wall Street Journal, 28 Oct. 2010.

the nearest office of DEA if the prescribing individual practitioner failed to deliver a written prescription to the pharmacy within seven days, in violations of 21 U.S.C §§ 8429(a)(1) and(a)(5);

- c. dispensed controlled substances to residents of long-term care facilities without prescriptions meeting the requirements of 21 C.F.R. §§ 1306.05(a) and 1306.11(f), including but not limited to dispensing controlled substances pursuant to pre-populated prescriptions prepared by the pharmacies and dispensing controlled substances pursuant to written orders that lacked one or more of the following: the signature of the practitioner, the date of issuance, the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, or the name, address and DEA registration number of the practitioner, in violation of 21 U.S.C § 842(a)(1);
- d. not maintaining records of prescriptions for controlled substances listed in Schedule II in compliance with 21 C.F.R. part 1304, in violation of 21 U.S.C. §842(a)(5).¹⁵³

304. In 2012, Omnicare paid \$50 million to resolve these allegations.

305. Since its acquisition by CVS, Omnicare has continued to violate the CSA. In 2020, Omnicare settled additional charges made by the DEA paying \$15.3 million. The DEA found that Omnicare violated the CSA:

in its handling of emergency prescriptions, its controls over the emergency kits, and its processing of written prescriptions that had missing elements. The federal

¹⁵³Settlement Agreement between DEA and Omnicare dated May 10, 2012.

investigation found that Omnicare failed to control emergency kits by improperly permitting long-term care facilities to remove opioids and other controlled substances from emergency kits days before doctors provided a valid prescription. The investigation also revealed that Omnicare had repeated failures in its documentation and reporting of oral emergency prescriptions of Schedule II controlled substances.¹⁵⁴

306. Many of these recent allegations made by the DEA repeat precisely those violations Omnicare engaged in before 2012. The Acting Administrator of the DEA stated, “Omnicare failed in its responsibility to ensure proper controls of medications used to treat some of the most vulnerable among us.”¹⁵⁵ CVS, fully aware of the past compliance failures and fully aware of the enormous danger posed to the public from the diversion of opioids, failed to properly monitor and create a corporate system through which it could ensure that its subsidiaries complied with the CSA.

d. CVS’s Violations of Its CSA Duties as a Distributor and as a Dispenser Caused Excessive and Unreasonable Amounts of Opioids to Be Shipped to and Dispensed from CVS Pharmacies in South Carolina, Missouri and throughout the United States.

307. CVS violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

308. CVS funneled far more opioids into South Carolina, Missouri and throughout the United States than could have been expected to serve legitimate medical use, including but not limited to suspicious orders.

309. It cannot be disputed that CVS, was aware of the suspicious orders that flowed

¹⁵⁴Press Release May 13, 2020, “Omnicare, Inc. agrees to pay more than \$15 million to resolve allegations it improperly dispensed narcotics at long term care facilities.”

¹⁵⁵*Id.*

from its distribution facilities into its own stores. CVS simply refused to identify, investigate, and report suspicious orders even though CVS knew, or should have been fully aware, that it was shipping excessive quantities of opioids into South Carolina, Missouri and throughout the United States, and that some of those opioids were likely to be diverted.

310. Upon information and belief, CVS failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

311. CVS did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

312. Because of its vertically integrated structure, CVS has access to complete information regarding red flags of diversion across its pharmacies in and around South Carolina, Missouri and throughout the United States, but CVS chose not to utilize this information and failed to effectively prevent diversion.

313. By 2009, CVS Pharmacy, Inc. owned and/or operated more than 9,000 pharmacies in the United States. According to its website, CVS now has more than 9,900 retail locations. At all times relevant herein, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or opioids.

314. "CVS Corporation," not any individual CVS store, is the DEA registrant for each of CVS's pharmacies across the country. CVS renews the DEA licenses for its pharmacies

through a “Registration Chain Renewal.” From October 2013 through December 2016, CVS headquarters paid more than \$5 million to renew the licenses for 7,597 CVS locations, including one or more CVS pharmacies in South Carolina and Missouri.

315. As described above, until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products (HCPs) from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II opioids from outside vendors, with Cardinal acting as its exclusive outside supplier for the entire period for which ARCOS is available. Upon information and belief, McKesson also acts or has acted as an outside vendor for CVS.

316. CVS Pharmacy, Inc. instituted, set-up, ran, directed and staffed with its own employees the majority of the SOM functions for its pharmacy stores.

317. CVS lacked meaningful policies and procedures to guide its pharmacy staff in complying with their CSA duties, even as they evolved over time. Not until 2012 did CVS create guidelines explaining in more detail the “red flags” or cautionary signals that CVS pharmacists should be on the lookout for in order to uphold their corresponding responsibilities to ensure that all controlled substances are only dispensed for a legitimate medical purpose. In addition, CVS knew, or deliberately turned a blind eye, to its pharmacies’ role in the oversupply of opioids. At the pharmacy level, discovery will reveal that CVS knew or should have known that its pharmacies in [AREA], and the surrounding area, including [location], were (a) filling multiple prescriptions for the same patient using the same doctor; (b) filling multiple prescriptions for the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f)

filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription “cocktails”;¹⁵⁶(g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. CVS had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that were not legitimate.

318. CVS failed to use data held at the corporate level to assist pharmacists in evaluating the propriety of the prescription opioids dispensed by its pharmacies. CVS’s later dispensing policies and procedures make clear that for the majority of the time CVS has been engaged in the sale and dispensing of opioids, there was no meaningful integration of data and information that was within the possession and control of CVS corporate personnel.

319. Notably, with respect to CVS’s suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Opinion and Order [Denying CVS’s Motion for Summary Judgment], MDL No. 2804, Doc.3099 (N.D. Ohio Jan. 27,2020).

¹⁵⁶According to definitions applied by CVS for suspicious order monitoring purposes, “cocktails for opioids are methadone, muscle relaxants, stimulants and benzodiazepines.”

A. Walgreens

320. Walgreens operates a number of pharmacies in South Carolina, Missouri and throughout the United States and has, at times, also acted as a wholesale distributor supplying opioids to those stores. Walgreens failed to comply with its CSA duties as a distributor to monitor for and refuse to ship suspicious orders, and it failed to comply with its CSA duties as a dispenser to ensure that only dispensed legitimate opioid prescriptions. This conduct by Walgreens resulted in excessive and unreasonable amounts of opioids to be shipped to and dispensed in South Carolina, Missouri and throughout the United States and caused Plaintiffs' damages.

a. Walgreens Dragged Its Feet on Developing a SOMs Program, Instead Relying on After-the-Fact Reports of "Excessive" Orders While Ignoring Red Flags.

321. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

322. Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period.

Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.¹⁵⁷

323. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient," in a May 2006 Letter of Admonition. The letter cited Walgreens for controlled substances violations at its Perrysburg, Ohio Distribution Center, but highlighted problems that went far beyond that particular facility.

324. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," though Walgreens failed to even examine anything other than the size of an order. When Walgreens updated its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another "three times" formula.

325. Even with its generous threshold, each Walgreens Suspicious Control Drug Order report could be thousands of pages or more in length.

326. Walgreens did not perform any due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports, but instead shipped the orders without review.

327. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until **after** the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported **when discovered**. 21 C.F.R. § 1301.74(b). In some instances,

¹⁵⁷1:17-md-2804, [Doc. 5716]. *Id* at page 202.

months may have elapsed between an order's shipment and its subsequent reporting to the DEA, given the requirement, described above, of two consecutive months of exceeding the three times multiplier to trigger reporting.

328. In September 2012, the DEA issued an immediate suspension order ("ISO") regarding one of Walgreens's three Schedule II distribution centers, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that Walgreens's Jupiter, Florida distribution center failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. The DEA stated: "Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies."

329. In the ISO, the DEA also specifically considered the Suspicious Control Drug Order reports and made numerous findings of fact and conclusions of law¹⁵⁸ regarding the reports and Walgreens's suspicious order monitoring system—applicable across Walgreens's operations. These findings showed beyond any doubt that Walgreens's SOM program was not in compliance with its regulatory obligations. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious

¹⁵⁸1:17-md-2804, [Doc. 5716]. *Id.* at page 202.

Control Drug Order reports. These “DC” (distribution center) systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are “more akin to supply warehouses,” are “not designed to be a backstop to pharmacists,” and that they are not well “equipped to ensure compliance” or to “assist in combatting controlled substance abuse,” and “do not have the ability to detect trends in local markets.”

330. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens’s DC level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being “suspicious” on the Suspicious Control Drug Order reports.

331. Walgreens’s documents effectively acknowledge that it did not begin creating a suspicious order monitoring [“SOM”] system until March 2008. Specifically, in March 2008, Walgreens finally formed a five department “team” to “begin creating” a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders from just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide, and from that point it took several more years to fully implement.

332. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens’s “three times” test, showing that Walgreens’s post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

b. Walgreens Knew Its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.

333. Walgreens knew its procedures were inadequate well before the 2012 ISO issued

334. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that “[t]he submission of a monthly printout of after-the-fact sales does not relieve the registrant of the responsibility of reporting excessive or suspicious orders.”¹⁵⁹ The DEA further advised Walgreens that, while “[a]n electronic data system may provide the means and mechanism for complying with the regulations...the system is not complete until the data is carefully reviewed and monitored by the registrant.”¹⁶⁰

335. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out.

336. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment. One of the managers for Walgreens’s Pharmaceutical Integrity (“RX Integrity”) Department stated that, when he was with the Loss Prevention Department, he “basically burned the data on a CD and sent it off. I didn’t dive into each individual report or CD” and that he “would look at it briefly, but just to see if the data transferred to the CD, but that’s about the extent.”¹⁶¹ In an errata submitted in connection with a deposition in the MDL, Walgreens acknowledged that it “is currently unaware of due diligence that was performed based on orders being flagged. ..”¹⁶²

337. In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA

¹⁵⁹1:17-md-2804, [Doc. 5716]. *Id.* at page 205.

¹⁶⁰*Id.*

¹⁶¹1:17-md-2804, [Doc. 5716]. *Id.* at page 206.

¹⁶²1:17-md-2804, [Doc. 5716]. *Id.* at page 206.

compliance.

c. Even as it Rolled Out its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.

338. Walgreens did not prioritize compliance when instituting its SOM system. Even as late as 2012, 2013, and 2014, Walgreens viewed the SOM system as an inventory-control mechanism rather than as a compliance-control mechanism.

339. Perhaps because keeping supply moving, as opposed to preventing diversion, was Walgreens's primary focus, the SOM program Walgreens slowly developed had significant gaps and loopholes. For example, for the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Cardinal and Amerisource Bergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.

340. The new SOM-lite system also allowed Walgreens's stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Additionally, stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

341. Further, although the new SOM algorithm identified more than 389 pages of suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its "three times" formulas and previously listed on its Suspicious

Control Drug Order reports and submitted to the DEA “on a monthly basis.” This “discrepancy” prompted an internal email from an employee in Walgreens’s Loss Prevention Department, to Walgreens’s Vice President, Distribution Centers and Logistics, suggesting that “the new system should be tested further and enhanced to provide broader coverage of controlled substance activity. The same e-mail stated that “we are not equipped to handle the 389+ pages of ADR4 [suspicious order monitoring] data which are compiled nationwide each week,” and asked if his department had “a resource available” to assist. An email in response “recall[ed] the old paper report as being inches thick” and an instruction “in 1985 not to review or contact anyone on the data,” and inquired, among other things, “[w]ho from your group has been reviewing the data collected for the past twenty-five years?” and “[a]t present is anyone doing any review on what would be considered suspicious quantities that are physically ordered and are releasing to stores?”

342. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens’s new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens’s policy of reducing and then filling and shipping suspicious orders without reporting them violated the law. Walgreens’s post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for controlled substances were “marked suspicious” by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

343. Walgreens cited two people as being primarily responsible for performing due

diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was “not equipped” to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 to 100 of the thousands of orders that were deemed suspicious under the new algorithm. Walgreens did not provide Ms. Martin access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order history for that store. If an order did not “make sense” to her based on those limited resources, she testified that she would call the store or district manager or pharmacy supervisor. She lacked authority to take “direct action” on an order.

344. In the ISO regarding the Distribution Center, the DEA found that Walgreens “failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels.” The DEA noted that “[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores.”

345. These failures reflect systemic failures of Walgreens’s SOM system that impacted its distribution in South Carolina, Missouri and throughout the United States. Walgreens admits that the SOM systems and procedures at all of its DCs were the same, including those at the facilities that shipped opioids into the communities of Plaintiffs’. Accordingly, it is not surprising that, in February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC in Ohio to those issued to the Jupiter DC in Florida.

Walgreens employees made plans in preparation for the Perrysburg DC being “shut down” by the DEA, like the Jupiter DC. Within weeks of receiving the six subpoenas and warrant, Walgreens decided to “discontinue distribution of controlled substances from the Perrysburg facility” in order to “eliminate any immediate need for further DEA administrative action” regarding the Perrysburg facility.

346. Walgreens has admitted that both the Florida and Ohio DCs distributed prescription opioids into South Carolina.

347. Even as of November 2012, Walgreens SOM program still did not halt suspicious orders for due diligence evaluation or report the orders as suspicious. Further, at that time, the program began to automatically reduce orders that violated ceiling thresholds.

348. In December 2012, a further enhanced SOM system flagged “14,000 items that the stores ordered across the chain that would have to be investigated” before they could be shipped. Walgreens admitted that yet again it did not have sufficient resources to timely review these orders. Walgreens noted that “[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances.” At the time these 14,000 orders were flagged Walgreens Rx Integrity Team was comprised of fewer than five people. Even at its height, Rx Integrity had only eleven employees. Instead of sufficiently staffing the SOM program, Walgreens recognized it had the ability to control its due diligence workload by increasing the stores’ ceiling levels, and thereby reducing the number of orders that would hit that ceiling and result in a flag.

349. As described below, Walgreens admits to failures in its suspicious order monitoring prior to 2012. Comparing the 2013 SOM system to the previous system, one of

Walgreens's Pharmaceutical Integrity Managers in August 2013 explained:

The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override. The purpose for this is to ensure we have performed adequate review before sending in additional inventory.

350. Yet, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

Walgreens never equipped its distribution operations to properly monitor for, report, and halt suspicious orders. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution all together. Walgreens stated that "while the financial impact of no longer . . . [self distributing] from the Walgreens DCs was taken into consideration, there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses."

d. Walgreens Failed to Put in Place Adequate Policies to Ensure Compliance with Its CSA Obligations for Dispensing Opioids.

351. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningfully apply those policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potentially illegitimate prescriptions.

352. From at least 2006 through 2012, Walgreens's GFD policies explicitly instructed pharmacists who "receive [] a questionable prescription" or otherwise were "unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription as normal." Further, though Walgreens's policies listed a handful of "questionable circumstances," such as "increased frequency of prescriptions for the same or similar controlled drugs by one prescriber[,] for large numbers of patients [,] for quantities beyond those normally prescribed," it is unclear what, if any, resources Walgreens

made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a pharmacist “confirm[ed]” the prescription as “valid,” by calling the prescriber. For example, in 2010 when a pharmacy manager expressed concern about significant numbers of opioid prescriptions from pain clinics, and being help responsible for “excessive c2 rx dispensing,” her district supervisor instructed her “not [to] refuse script for large quantities” but simply to “call the MD’s, document it on the hard copy [,] and that is all that is needed to protect your license.” Despite internally recognizing that “a prescriber of a controlled substance prescription [may be] involved in diversion”, Walgreens’s GFD policies continued to endorse calling the doctor as a greenlight to any “questionable” prescription.

353. In 2012, Walgreens finally removed the “process the prescription as normal” language from its formal GFD policies, admitting that under the law “it is not enough to get confirmation that the prescriber wrote the prescription.” However, Walgreens still failed to ensure it complied with its duties.

354. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present. As a CSA registrant, Walgreens was obligated, and failed, to implement policies and procedures at a corporate level to ensure that its pharmacies are complying with the CSA.

355. Indeed, during the course of a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had “no training” for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the

legitimacy of prescriptions coming from Florida, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’s attitude that profit outweighed compliance with the law or protecting public health.

356. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all “Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances,” requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide “compliance program to detect and prevent diversion of controlled substances as required by the . . . [CSA] and applicable DEA regulations.” Pursuant to the MOA, the “program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor- shopping and requests for early refills” as well as “routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA.” Further, Walgreens was required to “implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations.”

357. Walgreens would make more promises in a 2013 Memorandum with the DEA, described further below, related to failures to that lead to the ISOs described above.

358. Even after development and a relaunch of its GFD policy in response to settlements with the DEA, however, Denman Murray, Director of Rx Supply Chain Retail, stated in an MDL deposition that, “traditionally, we’ve always treated a controlled substance like any

other, [a] widget's a widget to the system.”¹⁶³

359. Further, after the GFD “relaunch” in April 2014, a Walgreens “RxIntegrity” presentation focused on Walgreens “Market 25,” but also assessing “average market” trends, reported that “pharmacists [were] not being too strict with GFD, nor [were] they losing volume.”¹⁶⁴

360. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were “challenged to get into the stores” and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a “high number of stores” and their time was consumed with “people processes, business planning, market and district meetings,” such that supervision in store was being handled informally by “community leaders” who have “limited formal authority.”

361. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens’s supervision and compliance failures continued. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient “store walk program” existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees

¹⁶³1:17-md-2804, [Doc. 5716]. *Id.* at page 213.

¹⁶⁴Market 25 consisted of Indiana, Kentucky, and West Virginia. Similar results reported for Market 3, Florida.

were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year.

Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure.

362. However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance ... [with] regulatory requirements in... pharmacy areas," substantially no dispensing compliance supervision occurred, outside of ensuring the pharmacy was verifying the patient's address on five sample prescription fills.

363. In 2014, Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors. In 2014, Rx Integrity noted dozens of stores dispensing opioids without performing the required checks. In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.

364. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with GFD policies with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

365. Walgreens Discouraged Outside Vendors from Exercising Their Own Oversight.

366. The “Big Three” wholesalers, Cardinal, McKesson, and AmerisourceBergen, gave deferential treatment to chain pharmacies, such as Walgreens. An internal Cardinal document for example, stresses that “certain chain pharmacies refuse to allow any sort of administrative inspection by Cardinal or to make certifications” and that large, national chains can “take their billions upon billions of dollars in business to any wholesaler in the country.”

367. Thus, for example, in 2008, Cardinal prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would “minimize the disruption” to retail chains and that they would “work together” with the pharmacies “to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt” business. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Such “early warnings” were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by “flagging the stores at 75%,” it could “avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA.”

368. Preferential treatment of Walgreens ultimately was not enough for Cardinal to keep Walgreens’s business, however. In 2013, Walgreens entered a ten-year agreement with AmerisourceBergen. The shift to AmerisourceBergen as its exclusive supplier prompted Cardinal to complain: “we bailed you guys out when you had your [DEA]issues.”

369. By 2017, Walgreens accounted for 30% of AmerisourceBergen's revenue.¹⁶⁵

Like Cardinal, AmerisourceBergen was also deferential, allowing Walgreens to police their own orders and block any order to AmerisourceBergen that would exceed AmerisourceBergen's threshold and trigger a suspicious order notice to be sent to DEA from AmerisourceBergen. Additionally, when AmerisourceBergen received orders from Walgreens "outside the expected usage," Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits set by its "order monitoring program" with Walgreens, and also provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.

370. Walgreens also previously owned 26% of AmerisourceBergen's stock, until recently reducing its shares in the company to approximately 15% in 2023. In 2018, after a coalition of AmerisourceBergen shareholders sought greater transparency from its Board related to the "financial and reputational risks associated with the opioid crisis," Walgreens, together with other insiders, reportedly leveraged this position to defeat the proposal, which enjoyed majority support among the independent shareholders.

e. Walgreens's Violations of Its CSA Duties as a Distributor and Dispenser Caused Excessive and Unreasonable Amounts of Opioids to Be Shipped to and Dispensed from Walgreens Pharmacies in South Carolina, Missouri and throughout the United States.

¹⁶⁵As a part of its distribution agreement, Walgreens gained purchase rights to AmerisourceBergen equity, allowing it to further participate in the prescription opioid shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 26% of AmerisourceBergen. As part of the transaction, Walgreens has the ability to nominate up to two members of the Board of Directors of AmerisourceBergen. Currently, Walgreen's Co-Chief Operating Officer sits on the AmerisourceBergen Board of Directors.

371. As a vertically integrated distributor and dispenser of prescription opioids, Walgreens knew or should have known that an excessive volume of pills was being dispensed into South Carolina and Missouri.

372. Walgreens violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

373. The volume of opioids Walgreens shipped into, and dispensed from locations in, South Carolina, Missouri and throughout the United States was so high as to suggest that not all of the prescriptions could be for legitimate medical use.

374. Yet, upon information and belief, Walgreens consistently failed to make suspicious order reports in South Carolina and Missouri. Instead, Walgreens funneled far more opioids into South Carolina, Missouri and throughout the United States than could have been expected to serve legitimate medical use.

375. Walgreens developed and maintained highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time and depicted the exact amounts of pills, pill type, and anticipated order threshold for its own stores.

376. Through this proprietary data, Walgreens had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in throughout the United States, including South Carolina and Missouri. It used this data to evaluate its own sales activities and workforce. Walgreens also was in possession of extensive data regarding individual doctors' prescribing and dispensing to its customers, the percentage of a prescriber's

prescriptions that were controlled substances, individual prescription activity across all Walgreens stores, and the percentages of prescriptions purchased in cash. Such data are a valuable resource that Walgreens could have used to help identify when prescriptions were not legitimate, but it did not.

377. Upon information and belief, Walgreens, by virtue of its data analytics, was actually aware of indicia of prescriptions that were not legitimate, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug “cocktails,” known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walgreens ignored these obvious red flags.

378. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

379. Upon information and belief, Walgreens failed to adequately analyze and address its opioid sales relative to: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy’s community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

380. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to conduct adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies

accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

381. Discovery will reveal that Walgreens knew or should have known that its pharmacies in South Carolina and throughout the United States were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription “cocktails”; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walgreens had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that were not legitimate.

382. Walgreens admits its role in the opioid epidemic, stating it has the “ability – and [] critical responsibility – to fight the opioid crisis” as the “nation’s largest pharmacy chain” in a time when “[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade” and “drug overdose deaths – the majority from prescription and illicit opioids” resulting in “more fatalities than from motor vehicle crashes and gun homicides combined.” Walgreens also admits the “opioid crisis” is caused by “misuse, abuse

and addiction” that result from the “flow of opioids that fuel the epidemic.”

C. Walmart

383. Walmart is the largest private employer in the United States by far. It employs more than 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Walmart chose to do nothing while hundreds of thousands of people were dying, and waited until 2014 to begin to take meaningful action. By that time, it was too late.

384. Walmart Lacked a Suspicious Order Monitoring System for Most of the Relevant Time Period.

385. Walmart self-distributed opioids to its retail stores. Specifically, Walmart operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018 when it ceased self-distributing controlled substances. Walmart’s conduct is particularly troubling given that it acted both as a self-distributing and dispensing pharmacy for such a long period of time.

386. Prior to 2011, Walmart had not designed any formal system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations.

387. Walmart has claimed that its hourly employees and associates—who were also responsible for filling orders at Walmart Distribution Centers—monitored the orders they were filling for unusual size, pattern, and frequency. Typically, this “review” involved between 700

and 800 orders a day.¹⁶⁶ Walmart has also claimed that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.¹⁶⁷

388. Upon information and belief, Walmart can produce no written evidence of any such instructions to Walmart associates, no evidence of any training that would be required to implement such a procedure, or anyone actually being alerted about an unusual order or performing any follow up inquiry.

389. Walmart failed to provide any guidance to the associates as to what constitutes a “suspicious” order. Instead, Walmart relied on its associates’ subjective judgment based on their “knowledge and experience” as distribution center employees. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to 2011.

390. Walmart purportedly implemented a “monitoring program” that would identify suspicious orders of controlled substances in 2011. This system purportedly was in place until 2015.

391. Walmart’s monitoring program was insufficient to identify suspicious orders of controlled substances. The program flagged only very large orders of controlled substances.

392. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders or more than 20 bottles (2,000 dosage units) that were 30% higher than a rolling four-week average for that item. Orders under 2,000 units per week were never flagged, meaning that a pharmacy could order 8,000 units per month without ever being flagged. Moreover, that meant that even if an order was more than 30% greater than the

¹⁶⁶1:17-md-2804, [Doc. 5716]. *Id* at page 221.

¹⁶⁷ *Id* at footnote 120. (“[I]f a quantity stood out that seemed to be not normal *or what they perceived as normal*, they would report that to one of the managers, and we would call the store and ask about, ‘Is this order correct?’” (emphasis added)).

four-week average, it could not draw an alert unless it also was more than 20 bottles.

393. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart **never** reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50 bottles threshold and shipped it. Walmart never reported cut orders to the DEA. Although information regarding flagged orders was available and sent daily to Walmart's headquarters in Arkansas (the "Home Office"), no one from the Home Office ever reviewed or took **any action** regarding flagged orders.

394. This practice continued until mid-2012, when Walmart implemented "hard limits" on opioid orders. Under this approach, weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles. Still, Walmart failed to report the orders to the DEA.

395. During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles. Specifically, an "Over 20 Report" was provided to the Home Office in the morning and if nothing was done by mid-afternoon, the orders were filled and shipped. Upon information and belief, there is no evidence of any order in fact being held or reviewed pursuant to this practice.

396. Further, cutting the order did not mean that the Walmart pharmacy would not receive the full supply. Walmart pharmacies also purchased opioids from outside suppliers, including McKesson and AmerisourceBergen. Pharmacies could place another order with these outside vendors to make up the difference, or in some cases, have orders fulfilled by both Walmart and a third-party distributor at the same time. Thus, even though Walmart had the ability to monitor such orders, it chose not to, which allowed its pharmacies to surpass its already

high thresholds by simply ordering drugs from a third party.

397. Walmart knew that its monitoring program was insufficient to fulfill its obligations to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. It also stated that it was “TBD” when Walmart would develop such a system. In June 2014, Walmart again acknowledged that it lacked a compliant monitoring program. Moreover, Walmart acknowledged in 2014 that it had “no process in place” to comply with government regulations and that this created the “severe” risk of “financial or reputational impact to the company.”

398. It was not until late 2014 that Walmart’s written policies and procedures required orders of interest to be held and investigated.

a. Walmart’s “Enhanced” Monitoring Program Failed to Remedy Deficiencies in its Monitoring Program.

399. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy’s order history for each controlled substance. The thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

400. Walmart’s corporate designee, testifying on its behalf in the MDL, conceded that thresholds were set for business purposes, not for the purpose of “main[taining] of effective controls against diversion . . . into other than legitimate . . . channels.” 21 U.S.C.A. §823(a)(1),

401. Further, for almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month). Accordingly, even when Walmart implemented a store specific policy that took into consideration a pharmacy’s order history, the

program was still woefully deficient because it did not account for changes in ordering patterns.

A pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed.

b. Walmart's Violations of Its CSA Duties as a Distributor and Dispenser Caused Excessive and Unreasonable Amounts of Opioids to Be Shipped to and Dispensed from Walmart Pharmacies in South Carolina, Missouri and throughout the United States.

402. Despite the sheer volume of opioids Walmart shipped into South Carolina, Missouri and throughout the United States, there was a failure to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

403. Yet, upon information and belief, Walmart consistently did not report suspicious orders in South Carolina, Missouri and generally throughout the United States. Instead, Walmart funneled far more opioids into South Carolina, Missouri and throughout the United States than could have been expected to serve legitimate medical use, and ignored other indicia of suspicious orders.

404. In South Carolina, Missouri and throughout the United States, Walmart violated the standard of care for a distributor by failing to: control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

405. Indeed, as a vertically integrated, national retail pharmacy chain, Walmart had the ability to detect inappropriate and excessive opioid shipments in ways third-party wholesale distributors could not by examining the dispensing data from their own retail pharmacy locations.

406. Given the volume and pattern of opioids distributed in South Carolina, Missouri

and throughout the United States, Walmart was, or should have been aware that opioids were being oversupplied into the state and should have detected, reported, and rejected suspicious orders. Yet, the information available shows it did not.

407. Walmart by virtue of the data available to it, was actually aware of indicia of illegitimate opioid prescriptions, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug “cocktails” known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walmart ignored these obvious red flags.

408. Walmart failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy’s community; (b) increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

409. Given Walmart’s retail pharmacy operations, in addition to its role as a wholesale distributor, Walmart knew or reasonably should have known about the disproportionate flow of opioids into South Carolina, Missouri and throughout the United States and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

410. Walmart, throughout the relevant time period, owned and operated pharmacies throughout the United States, including pharmacies in South Carolina and Missouri. Through its wholly owned or controlled subsidiary companies, Walmart operates over 4,500 retail pharmacies across the U.S., a mail-order pharmacy, a specialty pharmacy, and six pharmacy distribution centers that distribute to other Walmart entities.

411. Walmart set policies for its pharmacies at the corporate level.¹⁶⁸ Walmart also presented, through nationwide advertising, a public image of the safety and excellence of all the pharmacists the company hired. In a recruitment video for pharmacists on Walmart's YouTube channel, the company shows Walmart pharmacists speaking about working at the company: "the safety and the excellence we carry to our patients is phenomenal," adding that "the culture that our company has [is] respect for the individual, service, and excellence, and, of course, we always have integrity."¹⁶⁹ The commercial also states that Walmart's pharmacists "strive for excellence" and are "passionate about providing quality healthcare."¹⁷⁰

412. As a vertically integrated distributor and dispenser of prescription opioids, Walmart had unique insight into all distribution and dispensing level data, and knew or should have known that it was dispensing an excessive volume of pills into South Carolina, Missouri and throughout the United States.

413. Discovery will reveal that Walmart knew or should have known that its pharmacies in South Carolina, Missouri and throughout the United States were: (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines

¹⁶⁸1:17-md-2804, [Doc. 5716]. *Id.* at page 226, footnote 121. ("Walmart has adopted a uniform national policy that is designed to meet or exceed the federal rules and the laws of all states.").

¹⁶⁹Walmart, *Your Career as a Walmart Pharmacist* (Sept. 25, 2014), available at <https://www.youtube.com/watch?v=9VD12JXOzfs> (last visited May 13, 2020).

¹⁷⁰*Id.*

or prescription “cocktails”; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walmart had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that were not legitimate.

414. Yet, Walmart failed to put in place effective policies and procedures for the dispensing of prescription opioids and failed to provide adequate guidance to its pharmacists on dispensing opioids. Moreover, Walmart’s pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions a pharmacy filled and profit that the pharmacy generated. Upon information and belief, controlled substances were included in Walmart’s pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walmart’s drive for speed, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

415. Even when Walmart pharmacists suspected diversion based on an individual prescriber’s prescribing practices, for years, Walmart did not allow its pharmacists to request blanket refusals to fill. Walmart, however, had always had the ability to do so. Finally, in 2017,

Walmart implemented a policy by which individual pharmacists could request such blanket refusals, which would permit the pharmacist to refuse to fill future prescriptions from that prescriber without evaluating each prescription individually. In addition, Walmart also always had the ability to “centrally block” problematic prescribers across all Walmart and Sam’s Club pharmacies, but did not establish a procedure to do so until 2017. In the “Practice Compliance” document describing this policy, Walmart admitted that it may, “in certain situations,” have information about prescribing practices that is not available to individual pharmacists:

While pharmacists are in the best position to determine whether individual prescriptions are appropriate, *additional information may be obtained that is not available to our pharmacists*. Therefore, in certain situations, a prescriber may be identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers.

416. These systemic issues are reflected in numerous enforcement actions and investigations that demonstrate the Walmart put profits and sales ahead of compliance, its customers and communities, and public safety. In 2009, for example, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

(1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

417. In addition, a 2011 Memorandum of Agreement (“2011 MOA”) arising out of the investigation states that the DEA also learned that the same pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

418. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a “compliance program” states that it is applicable to “all current and future Walmart Pharmacy locations.”

419. Following the 2011 MOA, Walmart was supposed to revamp its dispensing compliance program, but still, its policies and procedures remained deficient.

420. Instead, systemic failures continued, and Walmart’s national corporate office not only failed to insist that Walmart implement adequate controls against diversion, they ignored concerns raised by Walmart pharmacists.

421. One internal document from 2015, for example, notes concerns from a Walmart pharmacist that “his leadership would not support his refusing to fill any ‘legitimate’ (written by a doctor) prescriptions and he stated that his current volume/staffing structure doesn’t allow time for individual evaluation of prescriptions[.]” When this pharmacist refused to fill a customer’s controlled substance prescription because the customer was attempting to fill it too soon, the Market Health & Wellness Director for that store complained to management that the pharmacist “sent a customer to a competitor” and “expressed significant concern about how ‘sending customers away’ would impact the sales figures for the store,” and insisted that “the store needs to fill every available prescription.”

422. In October 2018, the DOJ had evidence that Walmart pharmacies in Texas dispensed opioids that killed customers who overdosed on the drugs. “The pharmacists who dispensed those opioids had told the company they didn’t want to fill the prescriptions because they were coming from doctors who were running pill mills,” but their pleas “for help and

guidance from Walmart’s corporate office” fell on deaf ears.¹⁷¹ Pharmacists in a number of other states also sought help from Walmart’s corporate office, also to no avail. Walmart compliance officials failed to take action in response to these alarms. “Instead, they repeatedly admonished pharmacists that they could not cut off any doctor entirely.”¹⁷² Even if pharmacists believed the doctor was operating a pill mill, rather than providing genuine medical care, “[t]hey could only evaluate each prescription on an individual basis.”¹⁷³ In fact, a 2011 document from Walmart Regulatory Affairs regarding the “Proper Prescriber-Patient Relationship” stated, “Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber- patient relationship or a valid medical reason before refusing to fill.”

423. A Texas federal prosecutor, in connection with an investigation that began in 2016, described a systemic problem. The investigation showed Walmart’s issue was not a few rogue employees. Rather, “Walmart had a national problem.”¹⁷⁴ The investigation reportedly revealed that between 2011 and 2017, “Walmart pharmacists repeatedly filled prescriptions that they worried were not for legitimate medical purposes, including large doses of opioids and mixtures of drugs the DEA considered red flags for abuse.”¹⁷⁵ They did so even though Walmart pharmacists in Texas, Maine, North Carolina, Massachusetts, Kansas and Washington all “raised

¹⁷¹Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), <https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment>.

¹⁷²*Id.*

¹⁷³*Id.*

¹⁷⁴*Id.*

¹⁷⁵Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), <https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment>.

alarms to the company's national compliance department about doctors.”¹⁷⁶ Regarding one Texas doctor who was later convicted of illegal distribution of opioids, a Walmart pharmacist wrote; “*We are all concerned about our jobs and about filling for a pill mill doctor. . . Please help us.*”⁸⁴ Another described the same doctor as a “problem,” a “liability for us,” and a “risk that keeps [him] up at night,” cautioning “[t]his is a serious situation.”⁸⁵ Similarly, in September 2016, a Walmart pharmacist in Pennsylvania advised that a doctor was “under investigation by the DEA for what we believe is a pill mill operation,” and that Rite Aid had begun refusing to fill his prescriptions, prompting prescriptions from this prescriber, which were “*almost solely narcotic and controlled prescriptions*” to double.⁸⁶ Still, Walmart adhered to its policy of requiring a case-by-case analysis of each prescription from the suspected pill mill placed with any Walmart pharmacy; it would not block the prescriber in its system or allow a “blanket” refusal to fill. Walmart was more concerned with the potential sale than it was with dispensing an illegitimate prescription.

3. MULTIPLE ENFORCEMENT ACTIONS AGAINST THE PHARMACY DEFENDANTS CONFIRM THEIR COMPLIANCE FAILURES

424. The Pharmacy Defendants have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, Pharmacy Defendants have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Pharmacy Defendants. Upon information and belief, all Pharmacy Defendants

¹⁷⁶
Id.

have engaged in conduct similar that alleged below.

A. CVS

425. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations.

426. CVS is a repeat offender and recidivist: the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

427. Confirming its systemic failures to comply with its CSA obligations, CVS has repeatedly faced enforcement actions. In 2020, CVS's Omnicare subsidiary agreed to pay a \$15.3 million civil penalty as part of a settlement with the DEA resolving allegations that it improperly dispensed opioids and other controlled substances to long-term care facilities without a valid prescription.

428. In November 2021, a jury in an MDL bellwether case found that CVS had failed to comply with its CSA obligations and had dispensed red-flag prescriptions without appropriate due diligence.

429. In March 2019, CVS Pharmacy, Inc. (including all of its relevant subsidiaries and affiliates) entered into a \$535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island, acting on behalf of the United States and the DEA's Providence Office. In connection with the settlement, a DEA agent stated: "Pharmacies put patients at risk when they dispense Schedule II narcotics, which have the highest potential for abuse, without a valid and

legal prescription.¹⁷⁷

430. In August of 2018, CVS paid \$ 1 million to resolve allegations that CVS pharmacies throughout the Northern District of Alabama violated record-keeping requirements under the CSA and its implementing regulations, the largest civil fine paid in Alabama by a DEA registrant.

431. In June of 2018, CVS paid \$1.5 million to resolve allegations that CVS pharmacies in Long Island, New York failed to timely report the loss or theft of controlled substances, including hydrocodone, recognized as one of the most commonly diverted controlled substances.

432. In July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.¹⁷⁸

433. This fine was preceded by numerous others throughout the country.

434. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

435. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

436. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the

¹⁷⁷<https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filling-invalid-prescriptions>.

¹⁷⁸Press Release, U.S. Dep't of Just., U.S. Attorney's Office E. Dist. of Cal., CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act (July 11, 2017), <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act>.

state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

437. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.

438. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had record keeping deficiencies.

439. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids “based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need.”

440. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

441. In 2013, CVS agree to pay \$ 11 million to resolve allegations it violated the CSA

and related federal regulations at its retail stores: (1) creating and using “dummy” DEA registration numbers on dispensing records, including records provided to state prescription drug monitoring programs; (2) filling prescriptions from prescribers who lacked current or valid DEA numbers; and (3) substituting the DEA number of non-prescribing practitioners for the DEA numbers of prescribers on prescription records.

B. Walgreens

442. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

443. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history – \$80 million – to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales. These actions demonstrate Walgreens’s knowledge of, and disregard for, its obligations to comply with the CSA.

444. On September 30, 2009, the DEA issued an Order to Show Cause against a Walgreens retail facility in San Diego, California based in part on allegations that it was dispensing controlled substances, including opioids, to individuals that it knew or should have known were diverting the controlled substances. Although the Order addressed this specific location, the response, including Walgreens’s internal assessment of its compliance, or lack thereof, revealed systemic failures from which its Trumbull County pharmacies would not have

been exempt.

445. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement (“2011 MOA”) with the DEA arising from the San Diego OTSC and expressly agreed that it would “maintain a compliance program to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations” including regarding the dispensing practices at all of its nationwide pharmacies.

446. On September 14, 2012, however, the DEA also issued an *Order to Show Cause and Immediate Suspension Order* (“ISO”), described above against Walgreens’s Distribution Center in Jupiter, Florida, as well as Orders to Show Cause related to certain Walgreen’s pharmacies. Evidencing the existence of systemic failures, the ISO stated that, “[DEA’s] concerns with [Walgreens’] distribution practices are not limited to the six Walgreens pharmacies [discussed in the ISO].”

447. In 2013, Walgreens agreed to the largest settlement in DEA history at the time—\$80 million—to resolve allegations that it committed an unprecedented number of record keeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales. In addition to the monetary payment, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. The DOJ, in describing the settlement, explained that the conduct at issue included Walgreens’s “alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations and allowed Walgreens’s retail pharmacies

to order and receive at least three times the Florida average for drugs such as oxycodone.”¹⁷⁹

448. The settlement resolved investigations into, and allegations of, CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

449. As part of the 2013 MOA described above, Walgreens “acknowledge[d] that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA . . . and its implementing regulations.”¹⁸⁰ The 2013 MOA required Walgreens to, among other things, “maintain a compliance program in an effort to detect and prevent diversion of controlled substances” as required by law.¹⁸¹

450. Walgreens’s Florida operations at issue in this settlement highlight its egregious conduct regarding its failure to comply with the CSA in its dispensing practices. Walgreens’s Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

451. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. Yet Walgreens corporate officers

¹⁷⁹¹⁴² Press Release, U.S. Attorney’s Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep’t of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

¹⁸⁰ 1:17-md-2804, [Doc. 5716]. *Id.* at page 237.

¹⁸¹ *Id.*

turned a blind eye to these abuses. In fact, the long term Controlled Substance Compliance Officer¹⁸² at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’s attitude that profit outweighed compliance with the CSA or the health of communities.¹⁸³

452. Walgreens’s settlement with the DEA stemmed from the DEA’s investigation into Walgreens’s distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’s corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’s Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 180 oxycodone prescriptions per day.

453. An August 2013 email shows Walgreens understood the consequences of its actions, explaining that Walgreens’s “previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing products like Oxycodone.”¹⁸⁴

454. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts(\$200,000).

¹⁸²1:17-md-2804, [Doc. 5716]. *Id* at page 238.

¹⁸³*Id.*

¹⁸⁴*Id.*

455. The Massachusetts Attorney General’s Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

456. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients’ drug use patterns and didn’t use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.

457. The actions against Walgreens as both a distributor and a retail pharmacy demonstrate it routinely, and as a matter of standard operating procedure, violated its legal obligations under the CSA and other laws and regulations governing the distribution and dispensing of prescription opioids.

458. In August 2022, Judge Breyer in the Northern District of California, ruling in a bench trial, found that Walgreens had failed to comply with the CSA in its dispensing of controlled substances in San Francisco. The Court further held that “[t]he evidence presented at trial makes clear that Walgreens . . . which had a history of failing to comply with federal regulations, filled a significant volume of illegitimate opioid prescriptions.” No. 3:18-cv-07591-CRB, ECF No. 1578, at 95 (N.D. Cal. Aug. 10, 2022).

C. Walmart

459. In addition to the actions described above against Walmart, a prosecution against a Virginia prescriber revealed failures at Walmart pharmacies from 2007 to 2012. A Decision and Order in that case revealed that a Walmart pharmacy would fill prescriptions pursuant to a telephone message from a staff member of the prescriber, purportedly on behalf of the prescriber,

even though she failed to provide the prescriber's DEA number. Despite the absence of information required by DEA regulations, the Walmart pharmacy would fill the prescription.¹⁸⁵

460. By mid-November of 2008, three Walmart pharmacies had dispensed more than 200 hydrocodone prescriptions and refills on behalf of the prescriber. In 2012, the prescriber learned that someone was fraudulently using his DEA number. He called a Walmart pharmacy regarding refill requests faxed from his office, and advised "that somebody was fraudulently using [his] DEA number."¹⁸⁶ Although he asked that his DEA number be blocked, the same pharmacy still filled two prescriptions on his behalf after this alert. Although Walmart did not face sanctions for its conduct, the Opinion and Order described "the fact that prescriptions which were missing [the] Respondent's DEA number were routinely filling notwithstanding that they were facially invalid," and "that the prescriptions were for hydrocodone in quantities and dosings that were clearly outside the scope of what is usually prescribed by podiatrists" as "deeply disturbing."¹⁸⁷

461. Federal prosecutors had also taken action against five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to keep records required to help prevent diversion of controlled substances as required by the CSA. Specifically, "accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation

¹⁸⁵DOJ, DEA, Docket No. 15-26, [FR Doc. No. 2017-13158] Peter F. Kelly, D.P.M.; Decision and Order, <https://www.deadiversion.usdoj.gov/fedregs/actions/2017/fr0623.htm>.

¹⁸⁶<https://www.deadiversion.usdoj.gov/fed regs/actions/2017/fr0623 htm>

¹⁸⁷*Id.*

of the CSA.”¹⁸⁸ A U.S. Attorney further explained that “[b]ecause of the pharmacies’ lack of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted.”¹⁸⁹

D. Defendants Colluded to Circumvent Limits on Opioid Sales

1. DEFENDANTS WORKED TOGETHER
TO AVOID MEANINGFUL CONTROLS
ON THE DISTRIBUTION AND
DISPENSING OF OPIOIDS

462. Finding it impossible to legally achieve their ever-increasing sales ambitions, all Defendants engaged in the common purpose of avoiding meaningful controls on suspicious orders.

463. Wholesale distributors such as the Independent Distributor Defendants had close financial relationships with both the Manufacturing and Marketing Defendants and Pharmacy Defendants, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, “[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers’ stock.” *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D. C. 1998). Through their generic source programs, wholesalers are also able “to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers.” Wholesalers typically also offer marketing

¹⁸⁸ Associated Press, *Wal-Mart Settles Drug Records Accusation* (Jan 7, 2009), <http://prev.dailyherald.com/story/?id=262762>.

¹⁸⁹ *Id.*

programs, patient services, and other software to assist their dispensing customers.

464. The Independent Distributor Defendants had financial incentives from the Manufacturing and Marketing Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

465. The Manufacturing and Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Independent Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a “Contracts and Chargebacks Working Group,” suggesting it is a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors).” The transaction information contains data relating to the direct customer sales of controlled substances to “downstream” registrants, meaning pharmacies or other dispensaries, such as hospitals. The Manufacturing and Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

466. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. The manufacturers negotiated agreements whereby the Manufacturing and Marketing Defendants installed security vaults for the Independent Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

467. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the PCF and the HDA.

468. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

469. The Center for Public Integrity and *The Associated Press* obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.” Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.

470. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF. In 2012, membership and participating organizations included Endo, Purdue, Allergan and Teva. Each of the Manufacturing and Marketing Defendants worked together through the PCF. But the Manufacturing and Marketing Defendants

were not alone. The Independent Distributor Defendants actively participated in the PCF, at a minimum, through their trade organization, the HDA. The Independent Distributor Defendants participated directly in the PCF as well.

471. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Independent Distributor Defendants and several of the Manufacturing and Marketing Defendants, including Allergan, Endo, Purdue, Mallinckrodt, and Teva, were members of the HDA. Additionally, the HDA and each of the Independent Distributor Defendants, eagerly sought the active membership and participation of the Manufacturing and Marketing Defendants by advocating for the many benefits of members, including “strengthen[ing] . . . alliances.”

472. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HAD wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.” Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Manufacturing and Marketing Defendants and Independent Distributor Defendants.

473. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s businesses. For example, the manufacturer membership application must be signed by a “senior

company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

474. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale distributors, including the Independent Distributor Defendants AmerisourceBergen, Cardinal, McKesson, and their subsidiaries.

475. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Manufacturing and Marketing Defendants and Independent Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

476. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Independent Distributor Defendants advertise these conferences to the Manufacturing and Marketing Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.” The conferences also gave the Marketing and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.” The HDA and its conferences were significant opportunities for the Manufacturing and Marketing Defendants and Independent Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturing and Marketing Defendants embraced this opportunity by attending and sponsoring these events.

477. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.
- e. Contracts and Chargebacks Working Group: “This working group

explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

478. The Distributor Defendants and Manufacturing and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers” The Manufacturing and Marketing Defendants used this information to gather high-level data regarding overall distribution and direct the Independent Distributor Defendants on how to most effectively sell prescription opioids.

479. Taken together, the amount of interaction and the length of the relationships between and among the Manufacturing and Marketing Defendants and Independent Distributor Defendants reflect a deep level of cooperation between two groups in a tightly knit industry. The Manufacturing and Marketing Defendants and Independent Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Rather, these Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

480. The HDA and the PCF are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of the Manufacturing and Marketing Defendants and Independent Distributor Defendants were in

communication and cooperation.

481. Publications and guidelines issued by the HDA nevertheless confirm that the Manufacturing and Marketing Defendants and Independent Distributor Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances. As the HDA explained in an amicus brief, these Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

482. This statement by the HDA and the Industry Compliance Guidelines support the allegation that the Manufacturing and Marketing Defendants and Independent Distributor Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Manufacturing and Marketing Defendants and Independent Distributor Defendants found the same balance—an overwhelming pattern and practice of selling as many opioids as possible.

483. Defendants also worked together through HDA and the National Association of Chain Drugstores (“NACDS”). The respective CEOs of the HDA and NACDS have spoken with one voice with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Defendants worked together in other ways as well to mislead the public regarding their

commitment to complying with their legal obligations and safeguarding against diversion.

484. The Defendants' scheme had a decision-making structure driven by the Manufacturing and Marketing Defendants and corroborated by the Independent Distributor Defendants. The Manufacturing and Marketing Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and failing to identify suspicious orders and report them to the DEA.

485. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturing and Marketing Defendants and Independent Distributor Defendants did this through their participation in the PCF and HDA.

486. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase production quotas (or decreasing production quotas) due to suspected diversion.

487. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

488. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with

each other about the reporting of suspicious orders to ensure consistency in their dealings with the DEA.

489. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

2. CONCERTED EFFORTS OF ALL DEFENDANTS TO SUPPRESS EVIDENCE OF DIVERSION

490. In addition, all Defendants undertook concerted efforts to illegally suppress evidence of drug diversion, which they were obligated to report. Absent this concealment, physicians like Plaintiffs, on their own and through the PBMs and/or other agents or Defendants, would have been on notice that a significant amount of the opioid drugs prescribed were not prescribed for legitimate medical need but rather made their way to the black market.

491. Absent this concealment, Plaintiffs, the medical community, and society at large would have been better equipped to address the Opioid Crisis that caused Plaintiffs to sustain such significant damages..

3. DEFENDANTS WORKED TOGETHER TO INCREASE THEIR PROFITS AND LOBBIED AGAINST RESTRICTIONS ON OPIOID USE AND DEA ENFORCEMENT

492. Beginning as early as the 1990s, outside distributors, largely through the HDA, began to convene with the Pharmacy Defendants through NACDS to discuss “concerns regarding statutory requirements to report to DEA what are commonly referred to as suspicious orders.”

493. The DEA’s suspensions of the registrations of three major distributors in 2007 lit a fuse within the industry. The very real threat of DEA enforcement prompted a flurry of communications between NACDS members and members of the HDA, described above, as well as the now-notorious PCF, a forum run by opioid manufacturers. A goal of HDA, which it shared

with NACDS, was to “develop a comprehensive DEA strategy” to avoid enforcement actions against distributors.

494. The NACDS and Defendants’ other trade groups saw their role in influencing diversion policy as being one that was absolutely critical, considering all that was at stake. At times, these groups adopted militaristic strategies and used terminology ironically similar to the “War on Drugs,” developing “task forces” and viewing the DEA’s crackdown on distributors and chain pharmacies as an assault on the companies themselves. Only this time, the war was being waged against the very regulatory authorities and government entities fighting to deal with the ever-growing problem of abuse and diversion in this country:

To follow up from last week's Pain Care Forum meeting, NACDS is interested in organizing a Task Force to respond to efforts to reschedule combination hydrocodone products into Schedule II. At a minimum, NACDS would like to organize to prepare for the October FDA hearing on this topic, but also would like to be prepared for any additional legislation that may be considered.

NACDS has scheduled a conference call to organize the Task Force on July 26 at 10:30 a.m. The conference call number is: 888-450-5996, pass code: 608936#. Please email Kevin Nicholson at knicholson@nacds.org if you are interested in joining the Task Force but have a conflict for that time.

Kevin N. Nicholson, R.Ph., J.D.
Government Affairs and Public Policy
National Association of Chain Drug Stores
Tel: 703-837-4183

768. Manufacturers’ participation in Defendants’ trade groups as a means to effectuate favorable policies is clear when evaluated in the context of how Defendants and other stakeholders viewed the DEA’s attempts to curb the opioid epidemic.

I wanted to say hello and I'm sorry that DEA is being so aggressive with this Suspicious Orders stuff.

I heard about your Lakeland, Florida distribution center effective next Monday. They're not going after your Jackson, MS distribution center, are they?

I wish there was something I could do to help in this situation - we are all in the same boat.

Best regards,

Jack

Jack Crowley
Executive Director
CSA Compliance
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901
203-588-8613 (w)
203-273-2656 (c)

495. Walgreens, like the other Defendants, recognized the importance of being able to control and influence trade groups such as the NACDS in the context of influencing policy related to opioid drug abuse and diversion. The efforts taken by the NACDS and other trade groups on behalf of Defendants were so important to their bottom line that Defendants spared no expense in supporting such groups. Walgreens took a particularly aggressive view of this mutually beneficial relationship, at times, being its top donor across the country.

496. NACDS worked with the HDA, the Alliance to Prevent the Abuse of Medicines ("APAM"), and the PCF to support the Marino Blackburn Bill, also known as S.483 or the "Marino Bill." NACDS, and Defendants intended the Marino Bill to "tie the hands" of the DEA in its efforts to actively and aggressively address diversion and compliance with the CSA." NACDS worked together with others in the opioid supply chain to influence the language in the bill to make it most favorable for them and more restrictive on the DEA. Notably, masking the influence of industry, when the APAM was asked to sign on to a 2014 letter of support it was "signed by the Alliance, *not the individual members.*" The final letter that was sent to Senators

Hatch and Whitehouse was signed by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation.

497. The Marino Bill effectively removed the DEA's ability to issue immediate suspension orders regarding manufacturer or distributor registrations. The Marino Bill permitted a non-compliant registrant an opportunity to cure its noncompliance before the DEA could take enforcement action and changed the standard upon which revocation occurred. In the midst of a growing opioid crisis, the Marino Bill removed the most effective deterrent and constrained DEA enforcement actions. With respect to its efforts to tie the hands of the DEA in its ability to pursue and hold accountable Defendants and other stakeholders for violations of law related to the sale and distribution of prescription opioids, CVS appreciated NACDS's influence.

From: Schlaifer, Marissa C </O=CVSCAREMARK/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MARISSA.C.SCHLAIFER>
To: Kevin Nicholson
CC: Eric Juhl; Gibbons, Thomas J.; Burton, Larry
Sent: 10/28/2013 8:27:08 AM
Subject: RE: No Policy Council Call this Week - Additional Items and Materials

Kevin –

Good work on the changes to the Marino bill. After reviewing the revised bill, our attorneys identified that it would still require drug testing/background checks of distribution center employees. So, we'd still prefer that it be limited to new employees only.

Thanks for your work on this!
Marissa

498. CVS as a member of the HDA, NACDS and the APAM was actively involved in efforts to curb the enforcement power of the DEA in its support of the Marino Bill. Its history and ties to the HDA and NACDS run deep.

499. The APAM is a trade group launched in the fall of 2013 and comprised of members of the American Medical Association, Cardinal, CVS, HDMA, Prime Therapeutics and Teva Pharmaceuticals.

The Alliance to Prevent the Abuse of Medicines



500. CVS and Defendants used trade groups like the HDA, NACDS, and APAM to gain favorable results when it came to regulations and roadblocks that were seen as being in the way of the Defendants' ability to capitalize on the opioid business. In particular, CVS would often hide behind the APAM when it knew its position could be controversial as it related to abuse and diversion. This particular letter was one in support of the controversial Marino Bill, a bill that CVS fought hard to push through, supporting it on three different fronts.

From: Schlaifer, Marissa C </O=CVSCAREMARK/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MARISSA.SCHLAIFER>
To: Jenkins, Ann
Sent: 7/15/2014 5:16:24 PM
Subject: RE: Alliance: HR 4709 Sign On Letter to Speaker Boehner - Deadline tomorrow at 3p

Back to your question about whether the Alliance has signed rather than individual members:
It looks like they are proposing this because it's signing on to a group letter. If it's a letter from the Alliance, it's always signed by the individual members.

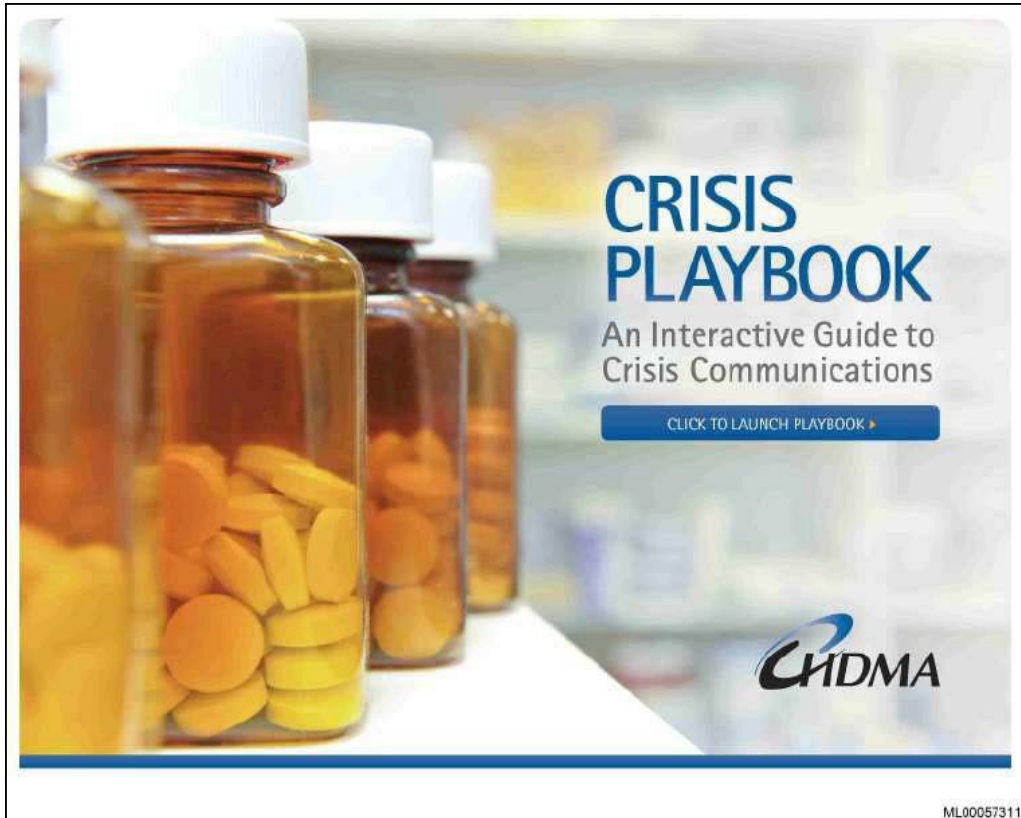
This might work for us since our name won't be on it ... but that's your call.

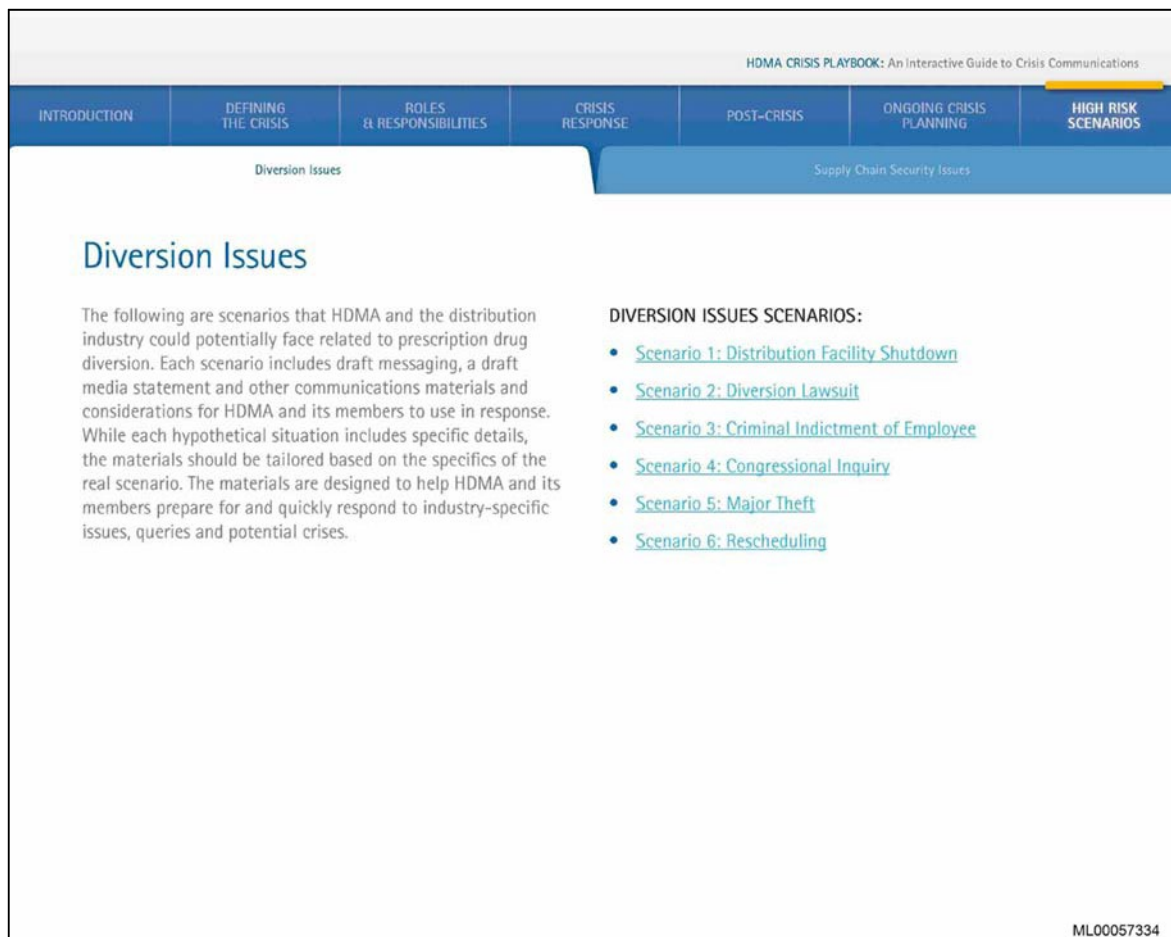
Marissa Schlaifer, R.Ph. | CVS Caremark | Head of Policy | 1300 I Street, N.W., Suite 525 West, Washington, DC 20005 | 202-772-3538 | marissa.schlaifer@cvscaremark.com

501. In August of 2011, NACDS worked with others on a joint letter opposing DEA fee increases for registrants that were intended to fund the "hir[ing of] more agents and do[ing] more inspections."

502. HDA's Crisis Handbook, developed in 2013, was a direct response to the

“threats” perceived by HDA’s members and affiliates, including Defendants, to their bottom line: profits derived from the distribution and sale of prescription opioids. Defendants, did and continue, to rely on and employ the strategies discussed in the Crisis Playbook. Curiously, there are no slides on how HDA and its members, including Defendants, might best work to curb the crisis that is the opioid epidemic.





503. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled prescriptions. NACDS also fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing what it described as “recent DEA actions in which DEA is expecting pharmacists to be enforcement agents” with respect to prescriptions for pain medications.

504. NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring the DEA to “work with the [Food and Drug Administration] on all drug diversion issues,” ostensibly on the grounds that the DEA’s diversion enforcement activities – including “clos[ing] drug distribution centers and pharmacies” and “actions against pharmacies” were harmful in “leading to patients not being able to receive their medications.” This purported

concern, however, was industry code for impediments to sales.

505. NACDS and HDA agreed that the pharmacies should “be more aggressive” and “lead the charge” with respect to certain DEA issues. NACDS members coordinated regarding pharmacy diversion and “DEA red flags” through a “DEA Compliance Workgroup.” Defendants further used a NACDS “Pharmacy Compliance Roundtable” to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council “Task Group” to “discuss issues and develop strategies” concerning “ongoing problems that NACDS members are having with DEA enforcement actions,” through which it sought to influence the government and media set meetings with legislators seeking to “address the problems with DEA actions,” and “collaborate with, and support others’ efforts” including HDA.

506. NACDS members coordinated regarding pharmacy diversion and “DEA red flags” through a “DEA Compliance Workgroup.” Defendants further used a NACDS “Pharmacy Compliance Roundtable” to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council “Task Group” to “discuss issues and develop strategies” concerning “ongoing problems that NACDS members are having with DEA enforcement actions,” through which it sought to influence the government and media’ set meetings with legislators seeking to “address the problems with DEA actions,” and “collaborate with, and support others’ efforts” including HDA.

4. DEFENDANTS KEPT CAREFUL TRACK OF PRESCRIBING DATA AND KNEW ABOUT SUSPICIOUS ORDERS AND PRESCRIBERS

507. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in

quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain that they fraudulently created and unlawfully fueled.

508. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including, but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “DataVendors”).

509. The Independent Distributor Defendants developed “know your customer” questionnaires and files. This information compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Independent Distributor Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The “know your customer” questionnaires informed the Independent Distributor Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

510. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors’ information purchased by the Defendants allowed them to view, analyze, compute, and

track their competitors' sales, and to compare and analyze market share information.

511. IMS Health (now IQVIA), for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.

512. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.

513. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.

514. According to testimony by the Cardinal Executive Chairman of the Board at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those provided by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports.

515. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

516. Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against distributors in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative

Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.

517. Moreover, the Manufacturing and Marketing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."

518. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]" She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report." This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was

shut down in 2010 to inform the authorities.

519. A Kadian prescriber guide discusses abuse potential of Kadian. It is full of disclaimers that Allergan has not done any studies on the topic and that the guide is “only intended to assist you in forming your own conclusion.” However, the guide includes the following statements: 1) “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and 2) “KADIAN may be less likely to be abused by health care providers and illicit users” because of “Slow onset of action,” “Lower peak plasma morphine levels than equivalent doses of other formulations of morphine,” “Long duration of action,” and “Minimal fluctuations in peak to trough plasma levels of morphine at steady state.”

520. Defendants’ obligation to report suspicious prescribing ran head-on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

521. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors’ sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

522. For example, at a national sales meeting presentation in 2011, Allergan pressed its sales representatives to focus on its high prescribers: “To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into ‘the big leak’. We need to fill the bucket faster than it leaks.” “The selling message should reflect the

opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions.” In an example of how new patients plus a high volume physician can impact performance: “102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week.”

523. The same is true for other Defendants. Teva directed its sales representatives to make a “minimum of seven Fentora calls per day” and focus “on high prescribers to maintain and grow their contribution.” Another chart showed Teva ensured that the majority highest-volume or “core prescribers” were detailed at least five times in ten months.

524. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

525. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company’s policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

526. Sales representatives making in-person visits to such clinics were likewise not fooled. But because pill mills were lucrative for the manufacturers and individual sales representatives alike, the Manufacturing and Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

527. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.” McKesson further admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300, *et seq.*, at the McKesson Distribution Centers.” Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities, some of which investigators found “were supplying pharmacies that sold to criminal drug rings.” Similarly, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

528. On December 23, 2016, Cardinal agreed to pay the United States \$44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)”;
- b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5)”;
- c. “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. § 828 and 21 C.F.R. Part1305.”

529. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4millionoxycodone pills during that time period. These quantities alone are sufficient to show

that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal settled for \$20 million.

530. Thus, as various governmental agencies have alleged or found – and as Defendants themselves have admitted – Defendants, acting in disregard of their duties, pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

5. DEFENDANTS ALSO ENTERED INTO JOINT VENTURES
THAT FURTHER UNDERMINED THEIR OUTSIDE VENDORS'
INCENTIVE TO CONDUCT DUE DILIGENCE, WHILE
INCREASING THEIR OWN ACCESS TO INFORMATION

531. The collaboration between Defendants and other industry partners extended beyond their mutual interest in limiting regulations and enforcement that constrained their ability to sell opioids. Indeed, the companies had direct financial relationships that, quite literally, invested them in each other's success.

532. As described above, Walgreens entered into an exclusive arrangement with AmerisourceBergen as its supplier, with Walgreens obtaining both equity in AmerisourceBergen and a seat on its Board. As part of a three-year extension of that arrangement, in 2016, the two agreed to include a requirement that AmerisourceBergen “make certain working capital investments in the relationship and will proceed with additional capital investments in its distribution network.”

533. The merger between Walgreens and AmerisourceBergen had begun in 2012, when the two formed Walgreens Boots Alliance Development, a joint venture based in Switzerland. AmerisourceBergen was described as being able to gain from Walgreens's “purchasing synergies” through the companies' relationship.

534. In 2014, CVS entered into a 50/50 joint venture with Cardinal to create Red Oak Sourcing, LLC (“Red Oak”). Red Oak uses the combined generic purchasing power of CVS and Cardinal to negotiate with generic drug manufacturers, and its website touts its management of a “multi billion dollar pharmaceutical portfolio.” To fund the venture, Cardinal would make quarterly payments of **\$25.6 million** to CVS, and also would contribute additional funds if the joint venture reached certain milestones.

535. In 2016, McKesson and Walmart formed Clarus One Sourcing Services LLP to source generic pharmaceuticals for their respective U.S. operations. As part of this “partnership,” McKesson and Walmart “established an organization in London to provide strategic sourcing services for both companies,” according to a job posting on McKesson’s website.

536. Given that Walgreens, CVS, Walmart, on the one hand, and the largest wholesalers, on the other, considered themselves partners invested in one another’s success, they had even less incentive to turn away from the blind deference the Pharmacy Defendants received when buying and selling controlled substances.

537. The Manufacturing and Marketing Defendants all marketed their products and disseminated their misrepresentations in the state(s) of South Carolina, Missouri and throughout the United States. The Independent Distributor Defendants all distributed opioids and failed to meet their regulatory obligations in South Carolina, Missouri and throughout the United States. The Pharmacy Defendants all distributed and/or dispensed opioids and failed to meet their regulatory obligations in South Carolina, Missouri and throughout the United States.

IV. DEFENDANTS CONSPIRED TO ENGAGE IN THE WRONGFUL CONDUCT
COMPLAINED OF HEREIN AND INTENDED TO BENEFIT BOTH
INDEPENDENTLY AND JOINTLY FROM THEIR CONSPIRACY

A. Conspiracy Among Manufacturing and Marketing Defendants

538. The Manufacturing and Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of prescription opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

539. This interconnected and interrelated network relied on the Manufacturing and Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Manufacturing and Marketing Defendants intended to mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

540. The Manufacturing and Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues, and profits centered around the development, dissemination, and reinforcement of several false propositions: (a) the risk of addiction from chronic opioid therapy is low; (b) to the extent there is a risk of addiction, it can be easily identified and managed; (c) signs of addictive behavior are "pseudo-addiction," requiring more opioids; (d) opioid withdrawal can be avoided by tapering; (e) opioid doses can be increased without limit or greater risks; (f) long-term opioid use improves functioning; and (g) alternative forms of pain relief pose greater risks than opioids.

541. The Manufacturing and Marketing Defendants knew that none of these propositions was true and that there was no evidence to support them.

542. Each Manufacturing and Marketing Defendant worked individually and

collectively to develop and actively promulgate these false propositions in order to mislead physicians, patients, health care providers, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

543. What is particularly remarkable about the Manufacturing and Marketing Defendants' effort is the seamless method in which the Manufacturing and Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Manufacturing and Marketing Defendants effectively built a new—and extremely lucrative—opioid marketplace for their select group of industry players.

544. The Manufacturing and Marketing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved goals which would have been impossible to meet by a single or even a handful of the network's distinct corporate members.

545. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Manufacturing and Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Manufacturing and Marketing Defendants.

546. The most unnerving tactic utilized by the Manufacturing and Marketing Defendants' network was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field and an unfounded theory or proposition would, or should, never gain traction.

547. Manufacturing and Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Manufacturing and Marketing Defendants were able to create a false consensus through their materials and references.

548. An illustrative example of the Manufacturing and Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter and Jick letter described above, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were *not* given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctors supervision.

549. Nonetheless, the Manufacturing and Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids despite its obvious shortcomings. The Manufacturing and Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users become addicted.

550. The Manufacturing and Marketing Defendants' collective misuse of the Porter and Jick letter helped the opioid manufacturers convince patients and healthcare providers that opioids were not a concern. The enormous impact of the Manufacturing and Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the *NEJM* on June, 1, 2017, describing the way the one-paragraph 1980 letter had

been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy . . .

551. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Manufacturing and Marketing Defendants committed overt acts in furtherance of their conspiracy.

B. Conspiracy Among All Defendants

552. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from opioid sales and their interrelated roles in the industry.

553. The amount of interaction and length of the relationships between and among Defendants reflect a deep level of cooperation between Defendants in a tightly knit industry. The Marketing, Independent Distributor, PBM, and Pharmacy Defendants were not separate groups operating in isolation or groups forced to work together in a closed system. They operated together effectively as a united entity, working alongside one another on multiple fronts, to engage in the fraudulent promotion and unlawful sale of prescription opioids.

554. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, including, for example, through membership in the

NACDS, PCMA, and HDA.

555. Defendants utilized their membership in the NACDS and HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach: to fail to identify, report or halt suspicious opioid orders so as to maximize the number of opioids manufactured, distributed, and dispensed, thus completing the circle of profit. The costs of which ultimately falling on the shoulders of Independent Emergency Room Physicians treating those with Opioid Use Disorder. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

556. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with the DEA.

557. The decision by all Defendants not to report suspicious orders had an additional effect: It would ensure that the opioid quotas allowed by the DEA remained artificially high and would deprive the DEA of any basis for refusing to increase opioid production quotas or decrease production quotas.

558. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

V. STATUTES OF LIMITATIONS ARE TOLLED, AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES

A. Continuing Conduct

559. Plaintiffs contend they continue to suffer harm from the unlawful actions by Defendants.

560. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The conduct causing Plaintiffs' damages remains unabated.

B. Equitable Estoppel and Fraudulent Concealment

561. Defendants are also equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiffs and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the government, Plaintiffs, and the community in which Plaintiffs provide emergency medical treatment, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the state and to continue generating profits. Notwithstanding the allegations set forth above, Defendants affirmatively assured the public, including the government, Plaintiffs, and the community in which Plaintiffs practice and provide emergency medical treatment, that they are working to curb the opioid epidemic.

562. Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and unlawful oversupply of opioids, all of

which fueled the opioid epidemic.

563. As set forth herein, the Manufacturing and Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Manufacturing and Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Manufacturing and Marketing Defendants' deceptions deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

564. Defendants also concealed from Plaintiffs the existence of Plaintiffs' claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated

misrepresentations misled regulators, prescribers and the public, including Plaintiffs, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

565. Plaintiffs did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

566. The Manufacturing and Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing throughout the country, including the communities in which Plaintiffs provide independent emergency medical treatment.

567. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the MDL Court ordered the transactional ARCOS data be produced, over Defendants' strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, Plaintiffs *could not identify* the potential defendants in this litigation, and further held that such information was "critical":

This means Plaintiff still does not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff[s] still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in [AREA] in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Walmart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, [AREA] (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation.

Discovery of precisely which manufacturers sent which drugs to which

distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiff[s'] claims, but also to the Court's understanding of the width and depth of this litigation.

Order of April 11, 2018 [ECF No. 233] at 6-7 (footnotes omitted).

568. Defendants intended that their actions and omissions would deceive Plaintiffs, who did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

VI. FACTS PERTAINING TO PUNITIVE DAMAGES

569. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Manufacturing and Marketing Defendants knew there was no support for their false and fraudulent claims about opioids. Yet, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

570. All of the Defendants, moreover, knew that unreasonably large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to control the supply of opioids. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that the flow of opioids would be unimpeded so that their profits would be maximized.

571. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and diversion schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and the risk of harm to public health and safety, and large-scale economic loss to communities and governmental entities

across the country, as well as to Independent Emergency Room Physician Plaintiffs. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Manufacturing and Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

A. The Manufacturing and Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

572. So determined were the Manufacturing and Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings, and prosecutions. These governmental and regulatory actions are described below.

1. FDA WARNINGS TO JANSSEN FAILED TO DETER JANSSEN'S MISLEADING PROMOTION OF DURAGESIC

573. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

574. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . .

unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.” The September 2, 2004, letter detailed a series of unsubstantiated, false, or misleading claims.

575. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been ““examining the circumstances of product use to determine if the reported adverse events maybe related to inappropriate use of the patch”” and noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

2. GOVERNMENTAL ACTION, INCLUDING LARGE
MONETARY FINES, FAILED TO STOP TEVA FROM
FALSELY MARKETING ACTIQ FOR OFF-LABEL USES

576. On September 29, 2008, Teva finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Teva trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.

577. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Teva continued its deceptive marketing strategy.

3. FDA WARNINGS DID NOT PREVENT TEVA FROM CONTINUING FALSE AND OFF- LABEL MARKETING OF FENTORA

578. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically denied Teva’s application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer BTP and use in patients who were not already opioid-tolerant.

579. Flagrantly disregarding the FDA’s refusal to broaden the indication for Fentora, Teva nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Teva against its misleading advertising of Fentora (“Warning Letter”). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden “the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case.” It further criticized Teva’s other direct Fentora advertisements because they did not disclose the risks associated with the drug.

580. Despite this warning, Teva continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Teva published an insert in Pharmacy Times titled “An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate).” Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: “It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain.”

4. A GUILTY PLEA AND A LARGE FINE DID NOT DETER
PURDUE FROM CONTINUING ITS FRAUDULENT
MARKETING OF OXYCONTIN

581. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, it misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

582. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other prescription opioid stakeholders, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions – eight times what the gun lobby spent during that period.

B. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain

583. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

584. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

585. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

586. Government actions against Defendants, including the Independent Distributor Defendants, with respect to their obligations to control the supply chain include:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain

effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone.
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone.
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone.
- e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone.
- f. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances

at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”).

- g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal’s Lakeland Facility for failure to maintain effective controls against diversion of oxycodone.
- h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

587. McKesson’s conscious and deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 McKesson MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.”

588. Despite its 2008 agreement with the DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the Controlled Substance Monitoring Program (“CSMP”) files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

589. On January 5, 2017, McKesson Corporation entered into an Administrative

Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA. McKesson's 2017 agreement with DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

590. As *The Washington Post* and *60 Minutes* previously reported, DEA staff recommended a much larger penalty than the \$150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

591. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.

* * *

They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in

the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.

[INTERVIEWER:] And they had none.

DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?

592. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the company's records show that the company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the company's compliance with the CSA and McKesson's 2008 settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 settlements and results of internal auditing, which revealed glaring omissions; specifically:

- a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";
- b. "[d]ocumentation evidencing new customer due diligence was incomplete";
- c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and
- d. The Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

593. Yet, instead of correcting these deficiencies, the shareholder action's description of McKesson's internal documents reveals that, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 settlements. During that period, McKesson's Audit Committee failed

to inquire whether the company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

594. In short, McKesson, was “neither rehabilitated nor deterred by the 2008 [agreement],” as a DEA official working on the case noted. Quite the opposite, “their bad acts continued and escalated to a level of egregiousness not seen before.” According to statements of “DEA investigators, agents and supervisors who worked on the McKesson case” reported in the *Washington Post*, “the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings.” “Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags.”

595. At a hearing before the House of Representatives’ Energy and Committee Subcommittee on Oversight and Investigations, on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken, Inc., another distributor, alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. He also testified that Miami-Luken had severed relationships with many customers that continue to do business with other distributors. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives’ answers confirmed gaps and breakdowns in past and current practices.

596. For example, Cardinal’s Executive Chairman, George Barrett, denied that

“volume in relation to size of population” is a “determining factor” in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious orders, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. In 2008, a Cardinal employee alerted the company to a pharmacy filling prescriptions for a known pill mill rejected by other pharmacies, Cardinal continued to supply the pharmacy for another six years. Cardinal increased another pharmacy’s threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

597. According to records produced to the Subcommittee, McKesson’s due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of a single two-page document. Despite McKesson’s claim that it reviewed every single customer for high volume orders for certain drugs, including hydrocodone and oxycodone, set a threshold of 8,000 pills per month, and examined and documented every order over that threshold, the company still shipped more than 36 times the monthly threshold to one pharmacy - 9,650 pills per day.

598. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or “80s,” as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers’ prescriptions.

599. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

600. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

601. The New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and yet that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

602. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

603. As all of the governmental actions against the Manufacturing and Marketing Defendants and against all the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

VII. ALTER EGOLIABILITY

604. To the extent that the wrongful acts or omissions alleged herein were committed or omitted by wholly-owned or majority-owned entities, the parent entities are liable for those acts or omissions as alter egos because (1) they dominated and controlled the wholly-owned or majority-owned entity and (2) exercised that domination and control to perpetrate a wrong or injustice. The details regarding the foregoing facts are particularly within the knowledge and control of the respective Defendants charged with wrongdoing and cannot be pleaded in greater detail by Plaintiffs without discovery.

A. Allergan plc Is Subject to Specific Personal Jurisdiction Under the Alter-Ego Theory

605. Allergan plc's¹⁹⁰ incorporation document, the Constitution of Allergan Public Limited Company Memorandum of Association, states that the Company was established "[t]o carry on the business of a pharmaceuticals company, and to research, develop, design, manufacture, produce, supply, buy, sell, distribute, import, export, provide, promote and otherwise deal in pharmaceuticals, active pharmaceutical ingredients and dosage pharmaceuticals."

¹⁹⁰ Allergan plc was formerly known as Actavis plc and is now known as Allergan Unlimited Company. To avoid confusion, Allergan plc/Actavis plc will be referred to as "The plc" or "the Company" for the purposes of this section, except as required by a direct quotation or context.

606. The plc's prior SEC filings provided that its "administrative headquarters" were in New Jersey.

607. Though incorporated in Ireland as a result of a 2013 corporate tax inversion, The plc never ceased running nationwide operations from its longstanding New Jersey home, including those related to the marketing and sales of opioids in Louisiana. As its Chief Executive Officer ("CEO") stated at the time of the inversion: "Everybody loves New Jersey too much, so nobody is willing to go."

608. Similarly, when The plc completed the acquisition of Allergan, Inc., The plc's CEO stated that it "remain[ed] strongly committed to Irvine," California, where Allergan, Inc. had maintained its headquarters. Prior to the Abbvie sale, The plc's top executives all worked in New Jersey.

609. In 2018, more than 77% of The plc's \$15.8 billion in net revenues came from the United States, with that 25% of its overall revenues deriving from a single customer head quartered in San Francisco throughout substantially all of the relevant time period— defendant McKesson Corporation ("McKesson").

610. Until 2016, The plc was the second largest manufacturer of generic opioids in the U.S. In 2016, it sold its generic drug business (including the generic opioid business) to defendant Teva Pharmaceuticals Ltd. for \$40 billion.

611. Allergan plc is the alter ego of its United States subsidiaries, with whom it shares a unity of interest and ownership.

612. A Management Service Agreement places American employees of U.S. subsidiaries, including defendant Allergan Sales, LLC, headquartered in Irvine, California, in charge of The plc's "executive management," "strategic direction," and "General and

Administrative Services.” The Management Service Agreement between The plc, Allergan Sales, LLC (headquartered in Irvine, California), and one other U.S.-based subsidiary puts the American employees of The plc’s subsidiaries in charge of, among other aspects of The plc’s operations, its “executive management,” “strategic direction,” and “General and Administrative Services.” And the enterprise-wide confidential accounting policies require The plc’s approval for “any new loan and/or cash movement” taken out or made by its subsidiaries.

613. The “Management Service Agreement” between The plc, on the one hand, and Allergan, Inc. and Allergan Sales, LLC on the other, shows that The plc was, and remains, an integrated group of entities with common decision makers, common office managers, and a common goal. The agreement puts the U.S. entities Allergan, Inc. and Allergan Sales, LLC in charge of The plc’s “executive management,” its “strategic direction in terms of business operations, financial goals and long-term growth,” and its “General and Administrative Services.” Thus, The plc is the shareholder (through a series of largely employee-less holding companies) of entities that, despite being far removed on the tax department organizational chart, manage it.

614. The corporate hierarchy from The plc to Allergan Finance, LLC proceeded through 11 entities incorporated in 4 countries: The plc (Ireland), Allergan WC Ireland Holdings Ltd. (Ireland), Warner Chilcott Limited (Bermuda), Warner Chilcott Holdings Company II, Ltd. (Bermuda), Warner Chilcott Holdings Company III, Ltd. (Bermuda), Allergan Ireland Limited (Ireland), Allergan Capital S.a.r.l. (Luxembourg), Allergan Pharma Inc. (Delaware), Allergan Akarna LLC (Delaware), and Allergan W.C. Holding Inc. (Delaware), to Allergan Finance, LLC (Nevada). Allergan Sales, LLC is four entities further down the chain: continuing from Allergan Finance, LLC to Allergan, Inc. (Delaware), and Allergan Holdco US, Inc. (Delaware) and

Allergan Holdings, Inc. (Delaware) jointly, to Allergan Sales. This permeable mishmash of responsibility, power, and control disproves Allergan's contention that The plc and its subsidiaries operate independently.

615. The plc regularly held itself out as the Allergan family entity with relevant information regarding opioids. For example, in response to a request seeking the prescribing information for the opioid Norco, a responsive letter providing that information was sent on Allergan plc letterhead. The letter also repeatedly references Allergan plc (and no other Allergan-related entity): "**Allergan, plc.** makes no recommendation regarding unapproved uses"; "Any publication of the provided information or use beyond this intent is prohibited without written authorization from **Allergan, plc.**"; "Thank you for your interest in **Allergan, plc.** products."

616. Internal emails concerning national opioids policies and opioid-related discussions were also circulated among persons located in the United States stating they worked for The plc:

- In 2017, the Executive Director, Customer Relations Operations at "**Allergan plc**" circulated a request seeking information about Allergan's suspicious order monitoring ("SOM") program, including emails from the DEA to block or stop sales, notations or emails regarding specific measures to monitor oxycodone, and other key information directly related to Plaintiffs' SOM-related allegations.
- In 2016, in response to an inquiry in *The Wall Street Journal* about the opioid Norco, the Director, Corporate Affairs for "**Allergan plc**" circulated an internal email including a draft response.
- In 2015, "the Vice President, Ethics & Compliance – Americas for **Actavis plc.**" sent a letter concerning the opioid hydrocodone to the Office of Criminal Investigations of the U.S. Food and Drug Administration ("FDA") and copying Joseph Rannazzisi of the DEA.
- In 2015, Senior Director for Clinical Development from "**Allergan plc.**" sent an email discussing "a consortium that deals with opioid REMS."
- In 2015, a Senior Scientist from "**ALLERGAN, plc.**" sent a request for a list of legacy Actavis/Watson-branded products, which included the opioids Kadian and Norco.

- In 2015, a Business Insights & Analytics employee from “*Allergan plc*” sent annual report information concerning the opioid Kadian.
- Regularly circulated “Daily Inventory Report[s],” some of which contained specific information about opioids, were sent widely (including to CEO Bisaro) by the Inventory Optimization Co-op from “*Allergan plc*.”

617. Invoices for opioid-related services were also sent by third parties to The plc. For example, in 2017, inVentiv Health Consulting – Risk and Program Management sent an invoice to *Allergan plc* for “ER/LA Opioid [Post-Marketing Requirements] February Fee Installment” and another for “Opioid [Post-Marketing Requirements] Support.”

618. The plc’s ledgers fail to appropriately account for all transactions it has with its subsidiaries. For example, The plc sold its “Global Generics Business” to defendant Teva for \$33.4 billion in cash and approximately \$5.4 billion in Teva stock. The 2013-2015 ledger shows only 18 transactions over a three-year period, a low number for a company that was, among other things, the third-largest generic pharmaceutical distributor in the United States.

619. Through the relevant time period, The plc’s administrative headquarters was located at the same address that fellow defendants Allergan Finance, LLC and Allergan Sales, LLC were located.

620. The plc “retained all of Actavis, Inc.’s officers in the same positions” upon its creation. And as of March 2018, six of The plc’s eight executive officers still served as the top officers of Allergan Finance, LLC.

621. The plc expressly adopted the debts and liabilities of Actavis, Inc.

622. When The plc was created to effectuate the merger of Actavis, Inc. and Warner Chilcott, each common share of Actavis, Inc. stock was converted into a common share of The plc stock on a one-to-one basis. The owners of Actavis, Inc. became the owners of The plc in equal measure. As such, ownership was identical.

B. Teva Ltd. Is Subject to Jurisdiction Where Its Subsidiaries Acted as U.S. Alter Egos

623. The acts carried out by Teva USA, Cephalon, and the Actavis Generic Entities directed at Louisiana—the marketing and sale of opioids in Louisiana, including misrepresentations to Louisiana providers, and failure to comply with the federal Controlled Substances Acts and Louisiana law for suspicious orders placed by its Louisiana-based customers—are properly attributable to Teva Ltd. via an alter ego theory.

624. Teva Ltd. exerts or has exerted sufficient control over Teva USA, Cephalon, and the Actavis Generic Entities to subject it to U.S. jurisdiction.

625. Teva Ltd. presents itself as a leading global pharmaceutical drug company and “one of the most competitive operational networks in the industry,” with 57,000 employees worldwide, 87 production sites, manufacturing 120 billion pills annually, distributing pharmaceuticals in approximately 100 markets globally, and having revenues of \$18.9billion.

626. Teva Ltd. is the leading generic drug company in the world, as well as in the United States, in terms of both total and new prescriptions.

627. Teva Ltd. has fully integrated Teva USA into its organizational structure, and Teva Ltd. and Teva USA present themselves as “One global brand, One story, One Teva.” One of Teva’s “core therapeutic areas” is pain, including opioid products.

628. Teva, through Teva USA, began selling its first opioid medications in the United States in July 1980 and started selling its first Schedule II opioids beginning in 1997. In early 2007, Teva Ltd. announced in a press release that it would continue to sell “its generic version of OxyContin tablets” in the United States through 2007, after settling a patent dispute with Purdue.

629. In 2016, Teva Ltd. saw so-called abuse-deterrent opioids as its chief opioid

money-making specialty opportunity under its pain segment.

630. Over the years, Teva Ltd. has built a vast portfolio of opioid products through various acquisitions of U.S. pharmaceutical drug companies.

631. In 2011, Teva Ltd. acquired Cephalon, and Teva USA immediately began selling its brand opioid products, Fentora and Actiq.

632. In 2016, Teva Ltd. acquired from Allergan plc its Actavis/Watson generic business, and Teva USA immediately began selling their generic opioid products.

633. Teva USA, Cephalon, and the Actavis Generic Entities are indirect subsidiaries of Teva Ltd. through several holding companies. Teva USA and Cephalon are sister corporations, while the Actavis Generic Entities are subsidiaries of Teva USA.

634. Teva Ltd. is managed by an Executive Committee (“Executive Management”), which consists of Chief Executive Officer Kare Schultz and 11 high-ranking Teva Ltd. corporate officers. All of these Executive Management officers are paid by Teva Ltd., whether employed in Israel, the United States, or Europe.

635. All Teva USA employees report up a chain through Teva Ltd.’s Executive Management and ultimately to Teva Ltd.’s CEO.

636. In addition to the global responsibilities of Teva Ltd.’s Executive Management, Teva Ltd. has employees around the world who have ultimate reporting responsibility for various operations and who in turn report to a Teva Ltd. Executive Manager. For instance, Teva Ltd.’s corporate designee, Doron Herman, is “S[enior] VP, Head of Global Tax, Teva Pharmaceuticals.” As Global Head of Tax, Mr. Herman is responsible for tax compliance and tax planning for Teva Ltd. *and* all its subsidiaries, and the Teva USA Head of Tax reports directly to him.

637. Teva Ltd. reports revenue by “segments.” Before 2018, segment revenue was reported by region (United States, Europe, and the Rest of the World) and by product type (*i.e.*, “Generics” and “Specialty”) and consolidated under “One Teva” as a single economic unit. In 2018, revenues were reported under three segments: North America, Europe, and International Markets.

638. Teva Ltd. controls the operations of its subsidiaries, or “regional commercial units,” through another layer of integrated management team via Global Divisions that it established, such as Teva Global Operations and Quality, Teva Global R&D, and many Global Departments or Support Functions including Finance, Legal, IT, Human Resources, Corporate Marketing and Communications Group, and the Business Strategy and Innovation Group. All are managed by Teva Ltd.’s global officers.

639. Teva Ltd.’s CEO is identified as the Chief Operating Decision Maker (“CODM”), and in a 2018 “Segment Memorandum,” Teva Ltd. stated that “the business will continue to be *managed and orchestrated by Teva’s CEO*, who regularly reviews its results, is directly involved in assessing performance and making decisions on overall resource allocation, and *ultimately responsible for* the allocation of resources. “Significantly:

- “The operating results of the component are regularly reviewed by the entity’s CODM to assess the performance of the individual component and make decisions about resources to be allocated to the component.”
- The CEO “reviews flash Reports” that contain key financial data such as “daily revenues . . . and sales information based on product line” and “presentations comparing actual results vs. Latest Best Estimates and Annual Operating Plan” for all “business segments or components.”
- “Decisions about Teva’s overall resource allocation are made by the CODM. . . Certain Decisions may be made at lower management levels (such as vice presidents, regional CEO’s etc.) where more detailed disaggregated information is reviewed, however the CODM is involved in assessing performance and making decisions on overall resource allocation.”

640. In 2017, Teva Ltd. announced “a new organizational structure and leadership changes to enable strategic alignment across our portfolios, regions and functions ***under this new structure our business will be integrated into one commercial organization.***”

641. Teva Ltd. maintains extensive financial control over its subsidiaries, including its U.S. subsidiaries in this action, and “enjoys substantial financial benefit from U.S. Subsidiaries and has [s]ole discretion over financing.”

642. Teva Ltd. files its financial results with the U.S. Securities and Exchange Commission (“SEC”) offsetting its losses against its gains as “One Teva” with “functional units unified organization,” “integrated into one commercial organization” as a single economic unit.

643. Teva Ltd., through its integrated management team, is involved in establishing its consolidated Annual Operating Plan (“AOP”) from the early stages of the AOP plan through final approval. The “AOP, as well as forecasts and budgets,” are consolidated and “are reviewed and approved by the CEO & BoD” and by Teva Ltd.’s outside auditors.

644. Teva Ltd., through its common officers, is also involved in approval of subsidiaries’ capital expenditures and procurement of supplies and services.

645. Teva Ltd. also securitizes the trade receivables of its subsidiaries so that they are controlled by Teva Ltd., not by its subsidiaries. To do this, Teva Ltd. “established a trade receivables securitization program” that took control and commingled its subsidiaries’ receivables and collections via a Special Purpose Entity (“SPE”) that it owns.

646. Teva Ltd. formed its SPE “for the sole purpose of purchasing trade receivables from Teva subsidiaries and the subsequent transfer of such receivables to BNP Bank conduit for a cash price less a discount.” The SPE is a Variable Business Entity and is owned and controlled by Teva Ltd., which is also the “primary beneficiary” of the SPE.

647. “Teva” is defined in Teva Ltd.’s SEC Form 10-K as “Teva Pharmaceutical Industries Limited and its subsidiaries.” “Teva” is defined variously elsewhere as Teva Pharmaceutical Industries Limited.

648. Even if the subsidiaries ultimately receive the collections from the SPE or Teva Ltd. (an element of commingling), SPE took control of the receivables and collections, and Teva Ltd. is the “primary beneficiary” of the SPE. Teva Ltd.’s U.S. subsidiaries essentially have mortgaged their future receivables and placed the proceeds in Teva Ltd.’s sole control and use; and they are protected from Teva’s U.S. subsidiaries’ creditors, including in bankruptcy.

649. Other indicia of financial control by Teva Ltd. over its subsidiaries include the following:

- Teva Ltd. used subsidiaries’ cash flows to repurchase its own shares
- Teva Ltd. used its subsidiaries’ cash flows to pay dividends to its shareholders
- Teva Ltd. imposed a Contract Policy so it controlled larger contracts signed by its subsidiaries to protect itself from third-party claims from those subsidiaries
- Teva Ltd. authorized a bonus policy applicable to all its employees, including its employees of its U.S. subsidiaries
- Teva Ltd. received tax benefits in Israel from owning its U.S. and other foreign subsidiaries in the same line of business under “One Teva”; and
- Teva Ltd. received tax benefits in the United States from the U.S. Tax Cuts and Jobs Act under “One Teva.”

650. Because it has near total domination and financial control over its subsidiaries, which it used to market and distribution massive quantities of opioids into the United States, including Louisiana, as further described herein, the exercise of personal jurisdiction over Teva Ltd. for the actions of its subsidiaries is warranted in this case.

651. In addition to Teva Ltd. having control over its subsidiaries’ operations and resources through Teva Ltd.’s CEO as CODM, and through the reporting lines through their corporate officers and Teva Ltd.’s Executive Management Team, Teva Ltd. further exerts control

over its subsidiaries in a number of other ways.

652. For example, Teva Ltd. maintains a Global Research and Development (“R&D”) “Division” under its control to dominate and control “its products formulation, development design of its generic and specialty pharmaceutical products . . . including products portfolio management and selection, and product launch and commercial execution.” “Global R&D is responsible for research and development of specialty products and includes regulatory affairs and pharmacovigilance,” and is managed by Dr. Hafrun Fridriksdottir, who is a member of Teva Ltd.’s Executive Management Team.

653. As a specific example of Teva Ltd.’s control over the products Teva USA markets, Teva had obtained approval from the U.S. Food and Drug Administration (“FDA”) of a specialty abuse deterrent opioid called Vantrela ER. On December 17, 2017, Brendan O’Grady, acting in his capacity as Teva Ltd.’s Executive V.P. and Head of North America, sent an e-mail to other members of Teva Ltd.’s Executive Management and others recommending that Vantrela not be launched due to lack of projected profitability. He wrote: “If we do not intend to launch and we have no potential buyer, my assumption would be that we pull the plug on the NDA but that is probably Kare’s [Teva Ltd.’s CEO Kare Schultz] call.” He further wrote, “let’s withdraw the file as Hafrun [Fridriksdottir] recommended.” In short, it was the recommendation of Teva Ltd.’s Executive Management, with Teva Ltd.’s CEO’s ultimate approval, that decided not to launch a Teva opioid product in the United States for which it already had FDA approval.

654. As a further example of Teva Ltd.’s control, Teva Ltd. has directed global pharmacovigilance and quality monitoring for its global subsidiaries, including for the United States. Teva Ltd.’s Head of Global Pharmacovigilance was Hedva Voliovitch, who worked out of Teva Ltd.’s offices in Israel. She also had authority to make binding decisions on Teva USA

related to safety information. No quality monitoring or pharmacovigilance was done in the United States. Teva Ltd. maintained the global adverse event database, including for opioids sold in the United States. Teva Ltd. also provided global standard operating procedures (“SOPs”) for pharmacovigilance and drug safety monitoring, and Teva USA was expected to comply with those SOPs. Pharmacovigilance was conducted by Teva Ltd.’s Global Patient Safety and Pharmacovigilance Department, including review of adverse events for opioid abuse. As of 2014, Ms. Voliovich was still the Teva Ltd. safety officer responsible for drug safety worldwide, including in the United States. Ms. Voliovitch also signed off as Teva Ltd.’s drug safety officer on an opioid to be sold in the United States.

655. Further, Teva Ltd., through its global officers and its staff, oversees, monitors, and audits its subsidiaries’ compliance to make sure that they are adhering to Teva Ltd.’s policies and standards established by Teva Ltd.

656. For example, Teva Ltd., through its Global Drug Safety and Pharmacovigilance Department, conducted an internal audit of Teva USA’s pharmacovigilance system in 2011. The audit states: “The safety system in Teva US has multiple gaps and the reporting of safety matters to the FDA . . . cannot be assured.” It further stated that: “The safety system in Teva US is largely out of control and the reporting of safety matters to FDA (and by extension other regulatory agencies and business partners) cannot be assured.”

657. Teva Ltd. also conducted at least one audit in 2015 of Teva USA’s U.S. DEA compliance department and suspicious order monitoring program. On August 19, 2015, Itai Rigbi, Teva Ltd.’s Senior Director, Global Internal Audit – Head of Operations and R&D, forwarded to McGinn and others the final August 19, 2015 Global Internal Audit report. That report found that the DEA Department was in “non-compliance with DEA requirements” and

was at “High Risk” of DEA enforcement action, and that the SOM program was at “Moderate Risk” for such action. These are critical areas, during a critical time period in the opioid crisis in which Teva Ltd. monitored safety with regard to its opioid products.

658. Teva Ltd. had other areas of direct control over its global and U.S. subsidiaries. For example, in 2016, Teva Ltd. implemented visual guidelines that governed all brand, visuals, and logos on all its subsidiaries to convey a consistent message about Teva products.

659. Teva Ltd. also imposed a Global Publication Policy on its subsidiaries with directives they were expected to follow.

660. Teva Ltd. also prepared and maintained a single Teva website portal that all subsidiaries were required to utilize.

661. Teva Ltd. has an insurance team that handles insurance for all its subsidiaries.

1000. Teva Ltd. established and implemented guidelines to dominate and control its subsidiaries through an integrated management system whereby the nomination of Board Members of First Tier Subsidiaries is subject to the approval of Teva Ltd.’s Secretary; sub- committee members of Teva Ltd.’s Executive Committee are selected by the CEO and approved by the Board of Directors (“Board”), which results in a management team with common officers who are officers of both Teva Ltd. and its U.S. subsidiaries. For “First Tier Subsidiaries” such as Teva USA and Cephalon, Teva Ltd.’s guidelines direct that “[a]t least one of the members will be a TEC [Teva Executive Committee] member responsible for the main activity of the subsidiary.” This refers to the main Teva Ltd. officers who are part of Executive Management reporting to Teva Ltd.’s CEO.

662. 1001. As a result of the “Guidelines,” nomination, selection, and approval process of Teva Ltd.’s Executive Committee and Sub-committee Members and management of

its Global Operations, Teva Ltd. itself created a management team with common officers who are officers of both Teva Ltd. and its U.S. subsidiaries. There are numerous Teva Ltd. employees who are also employees of Teva Ltd.'s U.S. subsidiaries. For example, Brendan O'Grady, who currently is a Teva Ltd. corporate officer and member of Teva Ltd.'s Executive Management reporting directly to Teva Ltd.'s CEO, is also an officer of Teva USA, as well as Teva's Actavis subsidiaries. And Sigadur Olafsson, Teva Ltd.'s former CEO, was Cephalon's President and Teva USA's President/Director/CEO.

663. Teva Ltd., through its overlapping officers, controls its subsidiaries' "Global Marketing," "Administration," R&D, purchase of supplies, raw materials and manufacturing of subsidiaries' pharmaceutical products, finance, and other significant supporting operations conducted in "shared and commingled assets," and created additional significant layers of controls via shared Global "Divisions" and Global Departments that it controls via its own officers. "Teva manages its assets on a company basis, not by segments, *as many of its assets are shared or commingled.*"

664. As part of its Global Operations, Teva Ltd. maintains offices worldwide with Teva employees supporting its subsidiaries through various departments, collectively identified as "Support Function Employees."

665. Teva Ltd. also has control of messaging about the opioid epidemic at the highest levels. On September 27, 2017, Yitzak Peterburg, Teva Ltd.'s CEO at the time, directed Teva Ltd.'s "Government Affairs: Opioid Workgroup" "to review the U.S. opioid epidemic and consider Teva response options." Debra Barrett, one of the meeting invite recipients, was head of Teva Ltd.'s global government affairs department and responsible for developing Teva Ltd.'s policy and lobbying in this area.

666. Teva Ltd.'s Board also had ultimate control of the firing of thousands of employees, including in the United States. In 2017, Teva Ltd.'s Board announced "a comprehensive restructuring plan" that included a "global workforce reduction of approximately 14,000 employees, more than 25% of our workforce."

667. Teva Ltd. exerted so much control over its U.S. subsidiary Defendants that the separate personalities of the entities no longer exist.

VIII. SUCCESSOR LIABILITY

668. To the extent that the wrongful acts or omissions alleged herein were committed or omitted by predecessor entities, their respective successor entities are liable for those acts or omissions because (1) they expressly or impliedly assumed the predecessor's liability, (2) there was a consolidation or merger of predecessor and successor, or (3) the surviving entity was a mere continuation of the predecessor. To the extent there was no formal merger of predecessor and successor, the respective successor entities are also liable for the wrongful acts or omissions of their respective predecessors based on the doctrine of de facto merger based on the factors of (a) continuity of ownership; (b) cessation of ordinary business and dissolution of the predecessor; (c) assumption by the successor of liabilities ordinarily necessary for the uninterrupted continuation of the business of the predecessor; (d) continuity of management, personnel, physical location, assets and general business operation of the predecessor, and (e) assumption of an identical or nearly identical name. The details regarding the foregoing facts are particularly within the knowledge and control of the respective Defendants charged with wrongdoing and cannot be pleaded in greater detail by Plaintiffs without discovery.

A. Allergan plc Is Subject to Specific Personal Jurisdiction as a Successor to Actavis, Inc.

669. The plc is also subject to jurisdiction because it was a successor to Actavis, Inc., *i.e.*, the transaction that formed The plc amounted to a consolidation, merger, or similar restructuring of the two corporations or the purchasing corporation was a mere continuation of the seller.

670. When The plc was created, each common share of Actavis, Inc. stock was simply converted into a common ordinary share of The plc. There was no cash consideration. Thus, the *sine qua non* of the consolidation or merger successor liability exists here.

671. The plc simply continued the business of Actavis, Inc. In its first SEC filing after creating The plc, the Company described itself in terms almost identical to the way Actavis, Inc. had been described. Actavis, Inc. said it was “a leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, branded generic, brand, biosimilar and over-the-counter (‘OTC’) pharmaceutical products.” So did The plc. The plc continues to refer to itself as a “U.S. pharmaceutical manufacturer[.]” in its SEC filings.

672. The plc’s SEC filings also defined references to “we, our, us, the Company or Actavis [to] refer to [the] financial information” of Actavis, Inc. for the period of time immediately before the creation of The plc, and defined such references to refer to The plc after its creation.

673. Moreover, despite transitioning from Actavis, Inc. to Allergan, the Company’s administrative headquarters and executives, and the substantial majority of its workforce, remained the same. Actavis, Inc.’s U.S. headquarters had been at Morris Corporate Center III,

400 Interpace Parkway, Parsippany, New Jersey; The plc's "administrative headquarters" continued to be located in precisely the same place.

674. That's because The plc was created to reduce the U.S. corporate income tax paid by Actavis, Inc. As described in a *Fortune* article titled, with aptly placed scare quotes, "Actavis: The latest Fortune 500 company to 'leave' the U.S. for tax reasons," none of Actavis, Inc.'s employees moved to Ireland. In fact, approximately 1,300 employees worked at The plc's administrative headquarters in New Jersey.

675. Indeed, the executive management of Actavis, Inc. merely rolled over and became the executive management of the newly created plc. The plc "retained all of Actavis, Inc.'s officers in the same positions."

676. And The plc maintained the "same website as Actavis, Inc."

677. Allergan corporate structure spread Actavis Inc.'s functions among several internal successors, including Allergan Finance LLC, that then shared power and responsibility. In fact, Actavis, Inc.'s responsibilities were divided between several successors, including Allergan Finance, LLC, The plc, and Allergan Sales, LLC.

678. Allergan Sales, LLC employed all of The plc's officers, paying those individuals to run "executive management," "strategic direction" and "General and Administrative Services" on behalf of the entire conglomerate from California. The Irvine facility has been the site of the majority of The plc's branded drug research and development.

679. The plc, in turn, succeeded Actavis, Inc. as the primary deal-making decision maker for its subsidiaries. For example, when Teva purchased the generic opioid portfolio, The plc reached down into and through various subsidiaries to select the particular assets to sell. In return, Teva paid (and then indemnified) The plc, *not* Allergan Finance, LLC, against liability in

opioids cases.

680. The plc is the executive center of the corporation, and it follows in the footsteps of Actavis, Inc. in that regard.

681. Last, The plc has expressly and impliedly assumed the liability of numerous defendants in this action. The plc expressly and impliedly adopted liability for Actavis, Inc.’s debts and liabilities. In The plc’s 2013 annual report, The plc stated it has “provided a full and unconditional guarantee of Actavis, Inc.’s obligations” for \$4.7 billion of debt, extending out to as far as 2042.

682. Further, the indemnification agreement between it and Teva implies The plc’s acknowledgment that it may be found liable for the actions of its former generic subsidiaries that were sold to Teva in 2016 for \$33.4 billion in cash and about \$5.4 billion in Teva stock.

683. Included in that sale was The plc’s generic opioid business – at the time, it was the second largest manufacturer of generic opioids in the United States. In 2018, The plc and Teva entered into a contract whereby Teva agreed to indemnify The plc for claims in opioid litigation related to the generic opioids it sold to Teva. The existence of such a provision implies that The plc acknowledges potential liability for actions related to its former generic opioid business in actions such as this one.

B. Teva Ltd. Is Subject to Jurisdiction as a Successor to Cephalon and the Actavis Generic Entities

684. The acts carried out by Teva USA, Cephalon, and the Actavis Generic Entities directed at Louisiana—the marketing and sale of opioids in Louisiana, including misrepresentations to Louisiana providers, and failure to comply with the federal Controlled Substances Acts and Louisiana law for suspicious orders placed by its Louisiana-based

customers—are properly attributable to Teva Ltd. via a successor-in-interest theory.

685. Teva Ltd. effectively assumed the liabilities of Cephalon and the Actavis Generic Entities via merger and continuation.

686. Teva Ltd. acquired Cephalon in 2011 for \$6.5 billion as the result of a merger between Cephalon and Teva Ltd. “Teva Pharmaceuticals Industries Ltd. announced today that it had completed its acquisition of Cephalon, Inc. Pursuant to the merger agreement between the parties, each share of Cephalon common stock has been converted into the right to receive \$81.50 in cash.”

687. Cephalon sold brand opioids (Fentora and Actiq) at the time of the merger with Teva Ltd., and Teva USA continued to manufacture, sell, and distribute these opioids after the merger. In addition, Teva USA has operated a combined SOM program.

688. Separately, Teva Ltd.’s Board approved the Master Purchase and Stockholder Agreement with Allergan plc to acquire the “Actavis Generics business” in August 2016 for \$40.5 billion.

689. On January 31, 2018, Teva Ltd. and Allergan plc agreed to a Settlement Agreement & Mutual Release. The Settlement Agreement states that: “Teva shall be responsible for the defense of Third-Party Claims involving opioid drugs to the extent such Third-Party Claims are based upon generic opioid drugs that are Products.”

690. Here, Teva Ltd. acquired the Actavis Generic Entities and absorbed them into Teva Ltd.’s global operations and assumed their liability in the opioid litigation.

691. Further, Teva Ltd. has previously and expressly stepped in and assumed the liabilities of its U.S. subsidiaries for other misconduct. For example, in an action by the Federal Trade Commission against Cephalon in 2015, Teva Ltd. agreed to submit to personal jurisdiction

of the district court and its order to pay \$1.2 billion in monetary relief.

692. Teva Ltd. is subject to jurisdiction through its predecessors because with Cephalon, it entered into a “Merger Agreement” approved by its Board, and with the Actavis Generic Entities, it acquired them from Allergan plc in 201 and agreed to indemnify Allergan plc for the liabilities those entities.

693. All of these U.S. subsidiaries were sellers of opioids in the United States, including in Louisiana, and after each merger or acquisition, Teva Ltd. took over the uninterrupted sale of their opioid products and absorbed them into Teva Ltd.’s global operations.

ADDITIONAL FACTS PERTAINING TO CLAIMS UNDER RICO

I. THE OPIOID ENTERPRISE

694. All Defendants joined together to form an association-in-fact enterprise (the “Opioid Enterprise”) for the common purpose of increasing and maintaining sales of prescription opioids for the financial gain of the members of the Opioid Enterprise.

695. Through their personal relationships, contractual relationships, and participation in groups like the PCF, HDA, NACDS, NWDA, and PCMA, and through their use of the same Front Groups and KOLs, Defendants had the opportunity to form relationships and agreements, and to take actions in furtherance of the Opioid Enterprise’s common purpose.

696. The “closed system” created by the CSA for the manufacture, distribution, and dispensing of controlled substances facilitated the creation of the Opioid Enterprise and the coordination between and among its members. Manufacturers, who were registrants under the CSA, could sell only to distributors and dispensers who were also registrants. Distributors, in turn, could sell only to dispensers who were also registrants. This “closed system” ensured a finite universe of participants as well as common regulatory oversight, which allowed

Defendants to form their association-in-fact and develop common “standards” and approaches, in which they would all work to maintain for the common purpose of increasing the sales of prescription opioids for their collective profit.

697. Defendants did not merely work separately or in parallel to accomplish their common purpose. Rather, Defendants recognized and understood that they needed to work together to subvert the limits placed on opioids as controlled substances in order to accomplish their goal of increasing opioid sales. Only through cooperative and coordinated actions could Defendants change the paradigm for opioid prescribing and ensure that their failures to provide effective controls against diversion would not be detected by others.

698. As alleged more fully below, each category of Defendants took actions to grow the market for prescription opioids and allowed every entity in the Opioid Enterprise to continue amassing profits. The Defendant members of the enterprise played different roles in bringing about their common purpose. Specifically:

- a. *Manufacturing and Marketing Defendants*: Manufacturing and Marketing Defendants, working with Pharmacy and the Major PBMs, engaged in a massive marketing campaign to promote prescription opioids as a class of drugs in order to increase the frequency and amount of opioid prescribing. Were it not for their marketing campaign, coordinated through their trade associations, Front Groups, and KOLs, the common purpose of the Opioid Enterprise could not have been fulfilled. Manufacturing and Marketing Defendants also coordinated with the other Defendants

regarding their common failure to identify, report, and halt suspicious orders of opioids, in order to ensure that controls against diversion did not interfere with increasing sales of prescription opioids.

- b. *Distributor Defendants*: Distributor Defendants coordinated with each other and with other Defendants through their trade associations to ensure a common course of conduct with respect to the identification, reporting, and halting of suspicious orders. Their conduct allowed every entity to continue to profit from the sale of prescription opioids. The common purpose of the Opioid Enterprise would have been thwarted if the Distributor Defendants, or any one of them, had reported and halted suspicious orders when others did not.
- c. *Pharmacy Defendants*: Pharmacy Defendants worked with Manufacturer and the Major PBMs to promote prescription opioids as a class of drugs in order to increase the frequency and amount of opioid prescribing. They also coordinated with other Defendants through their trade associations to ensure a common course of conduct with respect to the identification, reporting, and halting of suspicious orders (on the distribution side), and the treatment of red flag prescriptions (on the dispensing side).

699. There was regular communication between and among the Defendants in which information was shared, marketing campaigns were coordinated, and payments were exchanged. Typically, the coordination, communication, and payment occurred through the repeated and continuing use of the wires and mail, in which the Defendants shared information regarding overcoming objections and resistance to the use of opioids for chronic pain about suspicious orders, illegitimate prescriptions, and payments for prescription opioid sales. The Defendants functioned as a continuing unit for the purpose of accomplishing the Opioid Enterprise's common purpose, and each Defendant agreed and took actions to accomplish those purposes and continue the enterprise's existence.

II. DEFENDANTS CONDUCTED THE OPIOID ENTERPRISE'S AFFAIRS
THROUGH A PATTERN OF RACKETEERING ACTIVITY

700. Defendants used the Opioid Enterprise to perpetrate two unlawful schemes: the Opioid Marketing Scheme, and the Opioid Diversion Scheme. Through the Opioid Marketing Scheme, the Manufacturing and Marketing Defendants fraudulently promoted prescription opioids, disseminating the misrepresentations and omissions described above. Through the Opioid Diversion Scheme, all Defendants acted to evade the diversion controls on opioids sales, distribution, and dispensing required by the CSA, and fraudulently to portray themselves as being in compliance with the law. In perpetrating the Opioid Marketing Scheme and the Opioid Diversion Scheme, Defendants used fraudulent and unlawful means to accomplish the purpose of the Opioid Enterprise to increase sales of prescription opioids in order to extract greater profits for the members of the Opioid Enterprise.

701. As public scrutiny and media coverage focused on how opioids ravaged communities South Carolina, Missouri and throughout the United States, no member of the Opioid Enterprise challenged or corrected misrepresentations, sought to correct their previous

misrepresentations, terminated their role in the Opioid Enterprise, reported suspicious orders, refused illegitimate prescriptions, or publicly disclosed their conduct or participation in the Opioid Enterprise.

702. The impact of the Opioid Enterprise's schemes has been devastating, the effects of which remain felt throughout the country, injuring Plaintiffs in their business, causing economic loss, and consuming Plaintiffs' resources.

703. As a result, it is clear that the Defendants were willing participants in one or both of the Opioid Marketing Scheme and the Opioid Diversion Scheme, and the Defendants had a common purpose and interest in the objects of the schemes, and functioned within a structure designed to effectuate the Opioid Enterprise's common purpose.

704. In order to carry out the Opioid Marketing and Diversion Schemes, each Defendant conducted and participated in the conduct of the Opioid Enterprise through a continuing pattern of racketeering activity. Predicate acts making up this pattern included mail fraud, wire fraud, and felonious violation of the CSA and Code of Federal Regulations (CFR). The Manufacturing and Marketing Defendants used the mail and wire facilities of the United States in order to effectuate the campaign of fraudulent misrepresentations and omissions that constituted the Opioid Marketing Scheme. All Defendants used the mail and wire facilities of the United States in order to effectuate their scheme to evade the diversion controls required by the CSA. Defendants also violated the CSA in failing to comply with their obligations to provide effective controls against diversion. Defendants' felony violations involved multiple violations of the CSA and CFR that may be punishable as felonies as alleged below. All told, Defendants engaged in thousands of instances of mail fraud, wire fraud, and felony violation of the CSA and CFR.

705. The Defendants' predicate acts constituted a variety of unlawful activities, each of which was conducted with the common purpose of obtaining significant monies and revenues from the manufacture, distribution, and dispensing of prescription opioids. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

706. The predicate acts all had the purpose of contributing to the oversupply that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Enterprise.

707. Each instance of racketeering activity alleged herein was related, had similar purposes, and involved the same or similar participants and methods of commission. The Defendants calculated and intentionally crafted their schemes to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on Plaintiffs and the patients that they treat.

708. Indeed, as alleged elsewhere in this Complaint, Defendants were aware that the costs of their sought-after increases in opioid prescribing would be ultimately paid for by Independent Emergency Room Physicians treating those with Opioid Use Disorder.

A. The Opioid Marketing Scheme

709. In order to unlawfully increase the demand for opioids, the Manufacturing and Marketing Defendants perpetrated a scheme (the "Opioid Marketing Scheme") with each other, with the Major PBMs, Front Groups, and KOLs described above, and with certain unwitting participants. Through their personal relationships, participants in the Opioid Marketing Scheme had the opportunity to form and take actions in furtherance of the Opioid Enterprise's common

purpose. The Manufacturing and Marketing Defendants' substantial financial contributions as part of the Opioid Marketing Scheme, the contractual relationships between and among Manufacturer and Major PBM participants in the scheme to promote opioids, and the collective advancement of misleading opioid-friendly messaging together fueled the U.S. opioids epidemic.

710. The Manufacturing and Marketing Defendants' Opioid Marketing Scheme concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included, *inter alia*: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Manufacturing and Marketing Defendants named "pseudo-addiction"; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; and (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids.

711. The Opioid Marketing Scheme devised, implemented, and conducted by the Manufacturing and Marketing Defendants was designed to ensure that the Manufacturing and Marketing Defendants were able to unlawfully increase their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Manufacturing and Marketing Defendants' drugs. The Manufacturing and Marketing Defendants, Major PBMs, Front Groups, KOLs, and others acted together for the common purpose of increasing opioid sales and perpetrated the Opioid Marketing Scheme.

712. At all relevant times, the Front Groups were aware of the Manufacturing and

Marketing Defendants' conduct and were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Independent Emergency Room Physician Plaintiffs, as well as other healthcare providers. But for the Opioid Marketing Scheme, the Front Groups would have had incentive to disclose the deceit by the Manufacturing and Marketing Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Scheme and reaped substantial benefits.

713. At all relevant times, the KOLs were aware of the Manufacturing and Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The Manufacturing and Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Manufacturing and Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the Manufacturing and Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Physicians providing medical care for those with Opioid Use Disorder, including Plaintiffs. But for the Opioid Marketing Scheme, the KOLs would have had incentive to disclose the deceit by the Manufacturing and Marketing Defendants, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Scheme and common purpose, and reaped substantial benefits.

714. The Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and

KOLs engaged in certain discrete categories of activities in furtherance of the Opioid Marketing Scheme. Those activities involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; (4) efforts to limit prescriber accountability; (5) devising and executing plans to increase opioid use and sales, and circumvent CDC guidelines in doing so; (6) efforts to ensure that no UM would be placed on prescription opioids and that no Manufacturing and Marketing Defendants' prescription opioids would be disadvantaged against any others; and (7) ensure that prescriptions from Manufacturing and Marketing Defendants' mail-order pharmacies would be dispensed without any interruption.

715. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Scheme also functioned to criticize or undermine the CDC Guideline. Members of the Opioid Enterprise criticized or undermined the CDC Guideline, which represented “an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain.”

716. Several Front Groups, including the USPF and the AAPM, criticized the draft CDC guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”

717. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

718. The Manufacturing and Marketing Defendants alone could not have

accomplished the Opioid Marketing Scheme without the assistance of the Major PBMs, Front Groups, and KOLs, whose messaging and/or marketing activities were perceived as “neutral” and more “scientific” than the Manufacturing and Marketing Defendants themselves. Without the work of the Front Groups and KOLs, the Opioid Marketing Scheme could not have been achieved.

1. THE MANUFACTURING AND MARKETING DEFENDANTS’ CONDUCT IN THE OPIOID MARKETING SCHEME

719. From approximately the late 1990s to the present, each of the Manufacturing and Marketing Defendants exerted control over the Opioid Enterprise, participated in the operation or management of the affairs of the Opioid Enterprise, directly or indirectly, and worked towards achieving the Opioid Marketing Scheme in the following ways:

- f. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- g. Implementing various joint programs (between and among Manufacturing and Marketing Defendants and Major PBMs) with the goal of spreading deceptive, misleading, and unsupported messaging about the use of opioids to treat chronic pain and the risks of opioid addiction;
- h. Through information obtained pursuant to their contractual relationships (between and among Manufacturing and Marketing Defendants and Major PBMs), identifying and targeting the highest opioid prescribers with deceptive, misleading, and unsupported marketing material about the use of opioids to treat

chronic pain and the risks of opioid addiction;

- i. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- j. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- k. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- l. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Manufacturing and Marketing Defendants' messages about the use of opioids for chronic pain;
- m. Providing substantial opportunities for KOLs to participate in research studies on topics the Manufacturing and Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

- n. Paying KOLs to serve as consultants or on the Manufacturing and Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- o. Selecting, cultivating, promoting, creating, and paying Front Groups based solely on their willingness to communicate and distribute the Manufacturing and Marketing Defendants' messages about the use of opioids for chronic pain;
- p. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the Manufacturing and Marketing Defendants suggested or chose (and paid for) with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- q. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- r. Donating to Front Groups to support talks or CMEs that were typically presented over meals or at conferences;
- s. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- t. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- u. Developing and disseminating pro-opioid treatment guidelines with the help of KOLs as authors and promoters and Front Groups as publishers and supporters;
- v. Encouraging Front Groups to disseminate their pro-opioid messages to patient

groups targeted by the Manufacturing and Marketing Defendants, such as veterans and the elderly, and then funding that dissemination;

- w. Identifying high prescribers of opioids and disseminating marketing materials to those prescribers, and then funding that dissemination;
- x. Concealing their contractual and interpersonal relationships (between and among the Manufacturing and Marketing Defendants and Major PBMs) from the Plaintiffs and the public at large;
- y. Concealing their relationship to and control of Front Groups and KOLs from Plaintiffs and the public at large;
- z. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain, and causing such materials to be distributed through the U.S. mail and interstate wire facilities;
- aa. Communicating misrepresentations and pro-opioid messages to prescribers and pharmacies; and
- bb. Filling prescriptions without any interruption, including prescription that raised red flags about which pharmacists had conducted no due diligence.

720. The Opioid Enterprise members, to achieve the Opioid Marketing Scheme, had a hierarchical decision-making structure that was headed by the Manufacturing and Marketing Defendants and corroborated by the Major PBMs, KOLs, and Front Groups. The Manufacturing and Marketing Defendants controlled representations made about prescription opioids and worked together to conduct research using the Major PBMs' data, doled out funds to Major PBMs and payments to KOLs, and ensured that representations made by Major PBMs, KOLs,

Front Groups, and the Manufacturing and Marketing Defendants' sales detailers were consistent with the Manufacturing and Marketing Defendants' messaging throughout the United States. As described above, the Major PBMs were dependent on the other Manufacturing and Marketing Defendants for a significant amount of revenue received as a result of their collaboration. The Major PBMs, Front Groups, and KOLs in the Opioid Enterprise depended on the Manufacturing and Marketing Defendants for their financial structure and for career development and promotion opportunities.

721. The Front Groups also conducted and participated in the Opioid Marketing Scheme, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding opioids and the Manufacturing and Marketing Defendants' drugs that were consistent with the Manufacturing and Marketing Defendants' messages;
- b. The Front Groups distributed, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The Front Groups echoed and amplified messages favorable to increased opioid use and, ultimately, the financial interests of the Manufacturing and Marketing Defendants;
- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

- e. The Front Groups strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the Manufacturing and Marketing Defendants.

722. The Manufacturing and Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public – have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."¹⁹¹ "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."¹⁹²

- a. The KOLs also participated in the Opioid Marketing Scheme, directly or indirectly, in the following ways:
 - b. The KOLs promised to, and did, make representations regarding opioids and the Manufacturing and Marketing Defendants' drugs that were consistent with the Manufacturing and Marketing Defendants' messages themselves;
 - c. The KOLs distributed, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain

¹⁹¹*Fueling an Epidemic*, *supra* note 79, at 1.

¹⁹²*Id.* at 2.

outweighed the risks;

- d. The KOLs echoed and amplified messages favorable to increased opioid use and, ultimately, the financial interests of the Manufacturing and Marketing Defendants;
- e. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- f. The KOLs strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain; and
- g. The KOLs concealed their connections to the Front Groups and the Manufacturing and Marketing Defendants, and their sponsorship by the Manufacturing and Marketing Defendants.

723. The Opioid Marketing Scheme, devised and implemented by the Manufacturing and Marketing Defendants and members of the Opioid Enterprise, amounted to a common course of conduct intended to increase the Manufacturing and Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

724. The Manufacturing and Marketing Defendants worked together with each other through the Major PBMs to achieve the Opioid Marketing Scheme.

725. As discussed in detail above, various Front Groups, including APF, AAPM/APS, FSMB, APA, USPF, and AGS, were funded and controlled by Manufacturing and Marketing Defendants. The Front Groups, which appeared to be independent, but were not, transmitted

Manufacturing and Marketing Defendants' misrepresentations and joint promotional materials. The Front Groups thus worked together with Manufacturing and Marketing Defendants to perpetrate the Opioid Marketing Scheme.

726. The Manufacturing and Marketing Defendants worked together with each other through the Major PBMs, Front Groups, and KOLs to actualize the Opioid Enterprise's goals.

727. Similarly, as discussed in detail above, KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, were paid by Manufacturing and Marketing Defendants to spread their misrepresentations and promote their products. Manufacturing and Marketing Defendants and KOLs thus worked together to perpetrate the Opioid Marketing Scheme.

728. In Carrying out the Opioid Marketing Scheme, the Manufacturing and Marketing Defendants Engaged in a Pattern of Racketeering Activity

729. The Opioid Marketing Scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

730. The pattern of racketeering activity used by the Manufacturing and Marketing Defendants in the Opioid Marketing Scheme likely involved thousands of separate instances of the use of the U.S. mail or interstate wire facilities in furtherance of the unlawful Opioid Enterprise. These mailings and interstate wire transmissions included essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Manufacturing and Marketing Defendants' drugs induced by consumers, prescribers, regulators, and Plaintiffs' reliance on the Manufacturing and Marketing Defendants' misrepresentations.

731. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity, and, collectively, these violations constitute a pattern of racketeering activity, through which the Manufacturing and Marketing Defendants, in conjunction with the Major PBMs, Front Groups, and KOLs, defrauded and intended to defraud consumers, Plaintiffs, and other intended victims.

732. The Manufacturing and Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive, and effective use of opioids for long-term chronic, non-acute, and non-cancer pain. The Manufacturing and Marketing Defendants and members of the Opioid Enterprise knew that these representations violated the FDA-approved use of these drugs, and were not supported by actual evidence. The Manufacturing and Marketing Defendants intended that the Opioid Marketing Scheme to defraud would, and did, use the U.S. mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

733. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators, and the public, including Plaintiffs, the Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

734. The Manufacturing and Marketing Defendants' use of the U.S. mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, and

payments, including:

- a. Marketing materials about opioids, and their risks and benefits, which the Manufacturing and Marketing Defendants sent to health care providers and pharmacies, transmitted through the internet and television, published, and transmitted to Major PBMs, Front Groups, and KOLs located across the country and the United States;
- b. Written representations and telephone calls between the Manufacturing and Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between the Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and/or KOLs regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails, telephone, and written communications between the Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and/or KOLs, agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone, and written communications between the Manufacturing and Marketing Defendants, Major PBMs, Front

Groups, and/or KOLs, agreeing to or implementing the opioids marketing scheme;

- f. Contracts between Major PBMs and the Manufacturing and Marketing Defendants, setting out aspects of their collaboration as part of the Opioid Marketing Scheme;
- g. Communications between the Manufacturing and Marketing Defendants and/or Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Scheme;
- h. Communications between the Manufacturing and Marketing Defendants and/or KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Scheme;
- i. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the United States that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- j. Receipts of increased profits sent through the U.S. mail and interstate wire facilities – the wrongful proceeds of the scheme.

735. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Manufacturing and Marketing Defendants that misrepresentations would be published throughout the U.S. mail and by interstate wire facilities and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

736. To achieve the common goal and purpose of the Opioid Enterprise, the Manufacturing and Marketing Defendants and members of the Opioid Enterprise hid from the consumers, prescribers, regulators, and Plaintiffs: (a) the fraudulent nature of the Opioid Marketing Scheme; (b) the fraudulent nature of statements made by the Manufacturing and Marketing Defendants, and by Major PBMs, KOLs, Front Groups, and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between and among the members of the Opioid Enterprise.

737. The Manufacturing and Marketing Defendants and each member of the Opioid Enterprise agreed, with knowledge and intent, to the overall objective of the Opioid Marketing Scheme, and they participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

738. Indeed, for the Manufacturing and Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Manufacturing and Marketing Defendants each financed, supported, and worked through the same Major PBMs, KOLs, and Front Groups, and the Manufacturing and Marketing Defendants collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

739. The Manufacturing and Marketing Defendants' predicate acts all had the purpose of fraudulently increasing the opioid market, by, *inter alia*, increasing the number of opioid prescriptions. This scheme generated billion-dollar revenue and profits for the Manufacturing and Marketing Defendants at the expense of communities, consumers, and Plaintiffs, who paid for the related costs by treating those with Opioid Use Disorder, and were the ultimate bearer of the costs, and of the burden of the necessary medical treatment of the

Scheme. The predicate acts were committed or caused to be committed by the Manufacturing and Marketing Defendants through their participation in the Opioid Enterprise and in furtherance of its fraudulent Opioid Marketing Scheme.

B. The Opioid Diversion Scheme

740. For more than a decade, the Defendants worked together in the Opioid Enterprise to achieve the Opioid Diversion Scheme—conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market for prescription opioids that the law intended to restrict. The Defendants include three groups of entities: the Manufacturing and Marketing Defendants,¹⁹³ the Distributor Defendants,¹⁹⁴ and the Pharmacy Defendants.¹⁹⁵

741. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the CSA. Specifically, through the CSA, which created a closed system for controlled substances, Congress established an enterprise for good. The CSA imposes a reporting duty that cuts across company lines. Thus, regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate in an “anything goes” profit-maximizing market. Instead, the statute tasks them to watch over each other with a

¹⁹³Manufacturing and Marketing Defendants include Purdue, Cephalon, Janssen, Endo, Mallinckrodt, and Allergan.

¹⁹⁴Distributor Defendants include AmerisourceBergen (now Cencora), McKesson, and Cardinal Health, as well as the distribution entities for CVS, Walgreens, and Walmart.

¹⁹⁵Pharmacy Defendants include CVS, Walgreens, and Walmart.

careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct the enterprise to seek illegitimate profit at the expense of consumers and Plaintiffs, and others similarly situated.

1. THE DEFENDANTS' CONDUCT IN THE OPIOID DIVERSION SCHEME

742. As registrants under the CSA, the Manufacturing and Marketing Defendants and Distributor Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."¹⁹⁶ Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

743. As registrants under the CSA, the Pharmacy Defendants are obligated to ensure that they only dispense "to the extent authorized by their registration and in conformity with the [CSA]."¹⁹⁷ Each of the Pharmacy Defendants registered their pharmacies with the DEA to dispense Schedule II-V controlled substances. These DEA registrations authorized the Pharmacy Defendants' pharmacies to dispense controlled substance, which means "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner."¹⁹⁸ The CSA and Federal Regulations necessarily require pharmacies to investigate and perform due

¹⁹⁶ 21 C.F.R. § 1301.74(b).

¹⁹⁷ 21 U.S.C. § 822(b).

¹⁹⁸ 21 U.S.C. § 802(10); 21 U.S.C. § 829(a)-(b) (stating no Schedule II, III or IV drug may be dispensed without the written prescription of a practitioner, and that no Schedule V drug may be dispensed other than for a medical purpose); *accord* 21 U.S.C. § 823(f).

diligence on prescriptions before filling them, especially if they raise red flags. Prescriptions for which red flags cannot be resolved must be rejected.

744. The Major PBMs were also part of the Opioid Diversion Scheme. In addition to their role in the Opioid Marketing Scheme, the Major PBMs have and have had contractual relationships with and control dispensing at their in-network pharmacies: They install software on the in-network pharmacies' computers that purports to provide information as to when pharmacists should approve, reject, and/or conduct due diligence about prescriptions submitted to them. The Major PBMs also operate mail-order pharmacies which, like the retail pharmacies of the Pharmacy Defendants, are under obligations to only fill prescriptions that are issued pursuant to a lawful order of a practitioner.

745. Competition dictates that the Defendants would turn in their rivals when they had reason to suspect and/or learned about fraudulent statements made to the DEA, suspicious activity and/or ordering, or the filling of illegitimate prescriptions. Indeed, if any participant in the Opioid Diversion Scheme could gain market share or profit by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Unfortunately, however, that is not what happened. Instead, knowing that investigations and DEA enforcement would only lead to shrinking quotas and decreasing sales, the Defendants perpetrated a scheme that was designed to have the opposite goal of the CSA. Instead of carefully monitoring and potentially limiting the manufacture, distribution, and dispensing of controlled substances, the Defendants manufactured and distributed in disregard of suspicious activity, and dispensed opioids pursuant to illegitimate prescriptions and without conducting the requisite due diligence on red flags.

746. The Defendants' scheme required the participation of all. If any one Defendant

broke rank, its compliance activities would highlight deficiencies of the others and derail the goal of increasing and maintaining high quotas so that each member of the Opioid Enterprise could continue to profit from increased sales within their business line. But, if all the members of the enterprise conducted themselves in the ways described above, including with conduct that achieved nearly identical results within business lines (i.e., all Manufacturing and Marketing Defendants and Distributor Defendants refusing to report suspicious orders, and Pharmacy Defendants filling red-flagged prescriptions without conducting due diligence), it would be difficult for the DEA to go after any one of them or detect any impropriety from manufacture to dispensing. Accordingly, through the connections they made as a result of their participation in industry groups such as the Pain Care Forum (PCF), PCMA, HDA, and NACDS, with the active collaboration of the Major PBMs, the Defendants chose to flout the closed system designed to protect the citizens.

747. Publicly in 2008, for example, Defendants announced their formulation of “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances,” which was a joint effort of the Distributor Defendants with input and cooperation from the PCF, HDA, and NACDS. Privately, Defendants refused to act and, through their lobbying efforts, collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Yet, Defendants apparently all found the same profit- maximizing balance—

intentionally remaining silent to ensure the largest possible financial return.

748. As another example, common red flags of diversion are acknowledged in a “Stakeholders” memorandum created by a number of the Defendants, including the Pharmacy Defendants. Even though they were keenly aware of the oversupply of prescription opioids, Defendants continued to participate in and profit from this oversupply and ignore their pharmacies’ routine dispensing of red-flagged prescription opioids.

749. As described above, at all relevant times, the Defendants conducted the Opioid Diversion Scheme through the association-in-fact Opioid Enterprise, which scheme was perpetrated for the purpose of unlawfully increasing sales, revenues, and profits by lying to the DEA, failing to comply with their statutory and regulatory duties to identify and report suspicious orders, and failing to comply with their statutory and regulatory duties to perform adequate due diligence on red-flagged prescriptions and to refuse to fill those prescriptions without resolving red flags. Through their actions, the Defendants fraudulently increased the quotas set by the DEA that allowed them to collectively benefit from a greater pool of prescription opioids to manufacture, distribute, and dispense, and to profit from unrestricted and increasing sales of prescription opioids at every level of the supply chain—from manufacturing to dispensing. In support of this common purpose and fraudulent scheme, the Defendants jointly agreed to lie to the DEA and disregard their statutory duties to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, and to disregard their statutory duties to only fill legitimate prescriptions. The goal was to increase orders, and prescriptions, thereby enlarging the market for prescription opioids.

750. At all relevant times, as described above, the Defendants exerted control over, conducted, and/or participated in the Opioid Diversion Scheme as part of the Opioid Enterprise

by fraudulently claiming that they were complying with their respective duties under the CSA applicable to their respective business lines, including but not limited to: (1) identifying, investigating, and reporting suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and halting such unlawful sales so as to increase production quotas and generate unlawful profits; and (2) only filling legitimate prescriptions, conducting due diligence regarding prescriptions that presented red flags, and refusing to fill prescriptions for which red flags could not be resolved, as set forth below.

751. The Defendants disseminated false and misleading statements to state and federal regulators claiming that:

- a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- b. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- c. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids;
- d. they did not have the capability to identify suspicious orders of controlled substances;
- e. they were complying with their corresponding responsibility to conduct adequate due diligence when dispensing prescription opioids; and

- f. they were complying with their corresponding responsibility to refuse to fill prescriptions for opioids if red flags were not fully resolved.

752. Participants in the Opioid Diversion Scheme applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”¹⁹⁹ Pharmacy Defendant participants in the Opioid Diversion Scheme disregarded multiple federal regulatory enforcement actions aimed at rectifying their dispensing failures.

753. As described above, the CSA and the Code of Federal Regulations require the Defendants to conduct specific activities pursuant to their status as registrants. For the Manufacturer and Distributor registrants, the CSA and Code of Federal Regulations require them to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a felony criminal violation of the statute. The CSA and Code of Federal Regulations also require the Defendant pharmacies to meet their corresponding responsibility in dispensing such that they perform due diligence on any red-

¹⁹⁹HDMA is Now the Healthcare Distribution Alliance, Pharmaceutical Commerce, <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), <http://www.wvgazette.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->

flagged prescriptions and refuse to fill prescriptions for which red flags cannot be resolved. The failure to do so may also amount to a felony crime.

754. The Defendants knowingly and intentionally furnished false or fraudulent information to the DEA in their assay documentation and in reports about suspicious orders, and/or omitted material information from reports, records, and other documents required to be filed with the DEA, and all Defendants' applications for and renewal of their registrations. Specifically, the Defendants were aware of suspicious orders of prescription opioids, illegitimate prescriptions for prescription opioids, and the diversion of their prescription opioids into the illicit market through these suspicious orders and dispensing of illegitimate prescriptions, and yet they failed to report this information to the DEA and/or state regulators in their mandatory reports.

755. The Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their respective obligations under the CSA and Federal Regulations, and the actions necessary to carry out their common purpose of profiting from the illegal and increasing sale of prescription opioids.

2. IN CARRYING OUT THE OPIOID DIVERSION SCHEME,
DEFENDANTS ENGAGED IN A PATTERN OF
RACKETEERING ACTIVITY

756. The Opioid Diversion Scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

757. In devising and executing the illegal Opioid Diversion Scheme, the Defendants knowingly carried out a material scheme and/or artifice to defraud by means of materially false

or fraudulent pretenses, representations, promises, or omissions of material facts.

758. For the purpose of executing the illegal Opioid Diversion Scheme, the Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, as well as felonious violations of the CSA, constituted a pattern of racketeering.

759. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturing and Marketing Defendants, Distributor Defendants, Pharmacy Defendants, Major PBMs, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal Opioid Diversion Scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase, distribution, dispensing, and/or sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- f. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. §1301.74;

- g. Documents intended to facilitate the manufacture, distribution, and dispensing of the Defendants' prescription opioids, including assay information and/or reports, bills of lading, invoices, shipping records, suspicious order reports, due diligence reports, and correspondence;
- h. Payments from and to members of the Opioid Enterprise;
- i. Rebates and chargebacks from and to members of the Opioid Enterprise;
- j. Payments to the Defendants' lobbyists through the PCF;
- k. Payments to the Defendants' trade organizations, like the HDA, PCF, and NACDS, for memberships and/or sponsorships;
- l. Deposits of proceeds from the Defendants' manufacture, distribution, and dispensing of prescription opioids;
- m. Contracts negotiated and circulated between Major PBMs and their clients;
- n. Public representations and/or marketing materials by Major PBMs about their commitment to addressing misuse, abuse, and diversion of prescription opioids;
- o. Communications between Major PBMs and their clients;
- p. Transmission of payments between Major PBMs and their clients; and
- q. Other documents and things, including electronic

communications.

760. The Defendants (and/or their agents), for the purpose of executing the illegal Opioid Diversion Scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids, payments for prescription opioids, and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Purdue	(1) Purdue Pharma,LP, (2) Purdue Pharma,Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Teva	(1) Cephalon,Inc., (2) Teva Pharmaceutical Industries,Ltd., (3) Teva Pharmaceuticals USA,Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycodone	Oxycodone hydrochloride	Schedule II
	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II

Endo	Pharmaceuticals, Inc. (wholly-owned subsidiary of Endo)	Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt plc, (2) Mallinckrodt LLC (wholly-owned subsidiary of Mallinckrodt plc)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
	(1) Allergan plc f/k/a Actavis plc, (2) Actavis LLC, (3) Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., (4) Allergan Sales, LLC, (5) Allergan USA, Inc., (6) Allergan Finance, LLC, f/k/a/ Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., (7) Watson Laboratories,	Kadian	Morphine sulfate	Schedule II
		Generic Kadian	Morphine sulfate	Schedule II
		Norco	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

Allergan	Inc., (8) Warner Chilcott Company, LLC, (9) Actavis South Atlantic LLC, (10) Actavis Elizabeth LLC, (11) Actavis Mid Atlantic LLC, (12) Actavis Totowa LLC, (13) Actavis Kadian LLC, (14) Actavis Laboratories UT, Inc., (15) Actavis Laboratories FL, Inc.	Generic OxyContin	Oxycodone hydrochloride	Schedule II
Janssen	(1) Johnson & Johnson (2) Janssen Pharmaceuticals (3) Ortho-McNeil-Janssen	Duragesic	Fentanyl	Schedule II
		Nucynta	Tapentadol hydrochloride, immediate release	Schedule II
		Nucynta ER	Tapentadol hydrochloride, extended release	Schedule II

761. Each of the Defendants manufactured, distributed, paid for, dispensed, and/or received payment for the drugs identified above, throughout the United States.

762. The Defendants used the internet and other electronic facilities to carry out the Opioid Diversion Scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with federal and state laws regarding their manufacture of opioids, distribution of opioids, including the obligation to identify, investigate, and report suspicious orders of prescription opioids, prescription opioids for

an illegitimate medical purpose, and/or diversion of the same into the illicit market.

763. At the same time, the Defendants made multiple misrepresentations. Defendants misrepresented their compliance with distributions requirements, including the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all federal and state regulations regarding the identification and reporting of suspicious orders; and dispensing requirements to conduct due diligence on all red-flagged prescriptions and refuse to fill prescriptions for which red flags could not be resolved.

764. The Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid distribution, dispensing, sales, and to transmit payments and rebates/chargebacks.

765. The Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, pharmacies, PBMs, and other third-party entities in furtherance of the scheme.

766. The mail and wire transmissions described herein were made in furtherance of the Opioid Diversion Scheme and Defendants' common course of conduct to deceive regulators, the public, and Plaintiffs by convincing them that Defendants were complying with their federal and state obligations to identify and report suspicious orders of prescription opioids, and to only fill prescriptions written for a legitimate medical purpose and refuse to fill prescriptions for which red flags could not be resolved, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Opioid Diversion Scheme and Defendants' common course of conduct was to unlawfully manufacture, distribute, and

dispense an ever-increasing volume of prescription opioids—knowing that Plaintiffs and others would be the ones paying for the costs associated with increased opioid use.

767. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be fully alleged without further access to Defendants' books and records. However, Plaintiffs has described the types of and, in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

768. The Defendants did not undertake the practices described herein in isolation, but in cooperation with the entirety of the Opioid Enterprise, as part of the Opioid Diversion Scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, contributed to and/or participated in the scheme with Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for the Defendants.

769. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the manufacture, distribution, and dispensing of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

770. The predicate acts all had the purpose of contributing to the oversupply of prescription opioids. That oversupply substantially injured Plaintiffs' business and property both because Plaintiffs paid for over-prescribed, over-distributed, and over-dispensed opioids, and because that oversupply brought about the opioid epidemic and attendant medical costs also

borne by Plaintiffs. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Enterprise and in furtherance of its fraudulent Opioid Diversion Scheme.

771. As described herein, Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against Defendants supports this conclusion that the Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74, and otherwise flouting compliance requirements set in the wake of DEA enforcement actions related to their distribution and/or dispensing operations.

772. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiffs' businesses and Plaintiffs patients. The Defendants calculated and intentionally crafted their scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on the public, communities, and Plaintiffs. The Defendants were aware that Plaintiffs rely on these Defendants to maintain a closed system of manufacturing, distribution, and dispensing to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

773. By intentionally refusing to report and halt suspicious orders of their prescription opioids, and failing to comply with their corresponding responsibility and due diligence obligations in dispensing opioids, the Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 *et seq.* (Against Manufacturing and Marketing Defendants)

774. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

775. At all relevant times, the Manufacturing and Marketing Defendants were and are “persons” under 18.

776. U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

777. As alleged more fully herein, all Defendants (including the Manufacturing and Marketing Defendants) formed an association-in-fact enterprise, as described above as the Opioid Enterprise, for “the common purpose of expanding the prescription opioid market,” *In re Nat’l Prescription Opiate Litig.*, 2019 WL 4279233, at *2, in order to maximize profits for themselves in the promotion, sale, possession, distribution, and dispensing of controlled substances.

778. As alleged more fully herein, the Opioid Enterprise consisted of, *inter alia*, business and personal relationships formed through contractual negotiations, conduct, and racketeering activities consistent with and in advancement of the Opioid Enterprise’s purpose of expanding the prescription opioid market, and participation in and through both formal and informal coalitions and working groups.

779. The Manufacturing and Marketing Defendants conducted the Opioid Enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry out the Marketing Scheme. In furtherance of the Marketing Scheme, the Manufacturing

and Marketing Defendants disseminated multiple fraudulent misrepresentations and omissions, as described above, using the multiple channels described above.

780. Through these racketeering activities, the Manufacturing and Marketing Defendants sought to further the common purpose of the enterprise through the Opioid Marketing Scheme, a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the false propositions alleged earlier was true—all with the ultimate goal of inducing more opioid prescriptions, which the Enterprise members knew the medical costs associated with the increased use of Opioids would be paid for by medical providers like Plaintiffs. In so doing, each of the Manufacturing and Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Scheme by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

781. The success of Manufacturing and Marketing Defendants' common purpose depended upon Independent Emergency Room Physicians providing uncompensated treatment to individuals with Opioid Use Disorder. Uncompensated treatment provided by Independent Emergency Room Physicians allowed the Manufacturing and Marketing Defendants to increase and maximize sales of prescription opioids. IERPs such as Plaintiffs were the intended victims of Manufacturing and Marketing Defendants' common purpose.

782. The Opioid Enterprise alleged above is an association-in-fact enterprise whose Opioid Marketing Scheme consists of the Manufacturing and Marketing Defendants (Purdue, Teva, Janssen, Endo, Allergan, and Mallinckrodt); the Major PBMs (Express Scripts, OptumRx, and CVS Caremark); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

783. Each of the Manufacturing and Marketing Defendants and the other participants in the Opioid Marketing Scheme conducted and participated in the conduct of the Opioid Marketing Scheme by playing a distinct role in the scheme of maximizing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order to unlawfully increase the market for prescription opioids by changing prescriber habits and public perceptions.

784. Specifically, the Manufacturing and Marketing Defendants each worked together to coordinate the Opioid Marketing Scheme and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing, and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing, and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

785. Each of the Front Groups helped disguise the role of the Manufacturing and Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature" and "treatment guidelines" that promoted the Manufacturing and Marketing Defendants false messages.

786. Each of the KOLs were physicians chosen and paid by each of the Manufacturing and Marketing Defendants to influence their peers' medical practice by promoting the Manufacturing and Marketing Defendants' false message through, among other

things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the Manufacturing and Marketing Defendants' role in the enterprise and the enterprise's existence.

787. Moreover, each of the Manufacturing and Marketing Defendants, Major PBMs, KOLs, and Front Groups that furthered the Opioid Marketing Scheme had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed participants in the Opioid Marketing Scheme the opportunity to agree to conduct and participate in the scheme. Specifically, each of the Manufacturing and Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the Manufacturing and Marketing Defendants to advance the Opioid Marketing Scheme; each of the individuals and entities who formed the Opioid Enterprise and participated in the Opioid Marketing Scheme acted to enable the common purpose and fraudulent scheme.

788. At all relevant times, the Opioid Enterprise: (a) had an existence separate and distinct from each Manufacturing and Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the Manufacturing and Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Manufacturing and Marketing Defendants; (d) was characterized by interpersonal relationships between and among each participant in the Opioid Marketing Scheme, including between the Manufacturing and Marketing Defendants and each of the Major PBMs, Front Groups, and KOLs; (e) had sufficient longevity for the enterprise

to pursue its purpose and functioned as a continuing unit.

789. The persons and entities engaged in the Opioid Enterprise's Opioid Marketing Scheme are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the Manufacturing and Marketing Defendants.

790. The Manufacturing and Marketing Defendants conducted and participated in the Opioid Enterprise's Opioid Marketing Scheme through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

791. The Manufacturing and Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Manufacturing and Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Manufacturing and Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Enterprise, the U.S. mail, and interstate wire facilities.

792. The Manufacturing and Marketing Defendants participated in the scheme to defraud by using mail, telephones, and the internet to transmit mailings and wires in interstate or foreign commerce.

793. The Manufacturing and Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The Manufacturing and Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The Manufacturing and Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

794. Indeed, as summarized herein, the Manufacturing and Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions, and payments to carry out the Opioid Marketing Scheme.

795. Because the Manufacturing and Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Enterprise's uses of the U.S. mail and interstate

wire facilities (and corresponding predicate acts of mail and wire fraud) to perpetrate the Opioid Marketing Scheme have been hidden and cannot be alleged without access to the books and records maintained by the Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Enterprise alleged herein depended upon secrecy. However, Plaintiffs have described the occasions on which the Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and KOLs disseminated misrepresentations and false statements to consumers, prescribers, regulators, and Plaintiffs, as well as how those acts were in furtherance of the Opioid Marketing Scheme.

796. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in South Carolina, Missouri and throughout the United States, prescribers, regulators, and Plaintiffs. The Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and KOLs calculated and intentionally crafted the Opioid Marketing Scheme and common purpose of the Opioid Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the Manufacturing and Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the Manufacturing and Marketing Defendants' products.

797. The Manufacturing and Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Enterprise are separate and distinct from each other. Likewise, the Manufacturing and Marketing Defendants are distinct from the Opioid Enterprise.

798. The pattern of racketeering activity alleged herein has continued for well over a

decade, is continuing as of the date of this Complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

799. The racketeering activities conducted by the Manufacturing and Marketing Defendants, Major PBMs, Front Groups, and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators, and the Plaintiffs.

800. Each separate use of the U.S. mail and/or interstate wire facilities employed by Manufacturing and Marketing Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators, and the Plaintiffs. The Manufacturing and Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Enterprise.

801. Each of the Manufacturing and Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

802. As described herein, the Manufacturing and Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

803. The pattern of racketeering activity alleged herein has continued for well over a decade, is continuing as of the date of this Complaint, and, upon information and belief, will

continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

804. The Manufacturing and Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injury in their business and property. The Manufacturing and Marketing Defendants' pattern of racketeering activity logically, substantially, and foreseeably caused an opioid epidemic. Plaintiffs' injuries, as described below, were not unexpected, unforeseen, or independent. Rather, as Plaintiffs allege, the Manufacturing and Marketing Defendants knew that opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Manufacturing and Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry out the Opioid Enterprise's fraudulent Opioid Marketing Scheme, thereby increasing sales of their opioid products. It was foreseeable and expected that the Manufacturing and Marketing Defendants participating in the Opioid Enterprise through a pattern of racketeering activities to carry out the Opioid Marketing Scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.

805. It was foreseeable to the Manufacturing and Marketing Defendants and members of the Opioid Enterprise that Plaintiffs would be harmed when they engaged in the fraudulent schemes that form the common purpose of the Opioid Enterprise and the pattern of racketeering activities alleged herein. Indeed, extracting money from commercial payors like Plaintiffs was a primary goal of Defendants' racketeering activities.

806. Specifically, the Manufacturing and Marketing Defendants' participation in the Opioid Enterprise through a pattern of racketeering activities to carry out the fraudulent Opioid

Marketing Scheme has injured Plaintiffs in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid addiction epidemic.

807. Plaintiffs' injuries, as alleged throughout this Complaint and expressly incorporated herein by reference, include:

- a. Emergency Medical care, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths without compensation or reimbursement;
- b. Emergency Medical treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by a mother during pregnancy without compensation or reimbursement;
- c. Emergency Medical treatment for hospital and/or urgent care emergency department visits and other treatment for opioid misuse, addiction, and/or overdose without compensation or reimbursement;
- d. Emergency Medical treatment for infections related to opioid misuse, addiction, and/or overdose without compensation or reimbursement;
- e. Emergency Medical treatment for hospitalizations related to the misuse, addiction, and/or overdose of opioids without compensation or reimbursement;
- f. Costs for providing opioid overdose reversal medication such as Naloxone Hydrochloride (Narcan) without compensation or

reimbursement.

- g. Costs related to additional costs of hiring administrative staff in order to properly treat the increased number of individuals with Opioid Use Disorder seeking emergency medical treatment.
- h. Costs related to additional costs of hiring scribes needed to properly treat the increased number of individuals with Opioid Use Disorder seeking emergency medical treatment.

808. Plaintiffs' injuries were directly and proximately caused by Manufacturing and Marketing Defendants' racketeering activities because they were the logical, substantial, and foreseeable cause of Plaintiffs' injuries.

809. Plaintiffs are the most directly harmed entities, as Independent Emergency Physicians treat individuals with Opioid Use disorder disproportionately compared to all other medical professionals, and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

810. Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*, as appropriate:

- a. Actual damages and treble damages, including pre-suit and post-judgment interest;
- b. An order enjoining any further violations of RICO;
- c. An order enjoining any further violations of any statutes alleged to

have been violated in this Complaint;

- d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;
- e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;
- f. An order enjoining any future marketing of opioids through non-branded marketing including through the Major PBMs, Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;
- g. An order enjoining any future marketing to vulnerable populations, including, but not limited to, persons over the age of 55, anyone under the age of 21, and veterans;
- h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudo-addiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily

managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of function; (7) use of time-released opioids does not prevent addiction; (8) ADFs do not prevent opioid abuse; and (9) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

- i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;
- j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;
- k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;
- l. An order establishing a national foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;
- m. An order enjoining any diversion of opioids or any failure to

monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;

- n. An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;
- o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Opioid Enterprise, including any interest in property associated with the Opioid Enterprise;
- p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Opioid Enterprise as described in this Complaint, as the Court sees fit;
- q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;
- r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint as related to prescription opioids;
- s. Forfeiture as deemed appropriate by the Court; and
- t. Attorney's fees and all costs and expenses of suit.

SECOND CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 *et seq.* (Against All Defendants)

811. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

812. At all relevant times, the Defendants were and are “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

813. As alleged more fully herein, the Defendants formed an association-in-fact enterprise, as described above as the Opioid Enterprise, for “the common purpose of expanding the prescription opioid market” (*In re Nat’l Prescription Opiate Litig.*, 2019 WL 4279233, at *2) in order to maximize profits for themselves in the promotion, sale, possession, distribution, and dispensing of controlled substances.

814. As alleged more fully herein, the Opioid Enterprise consisted of, *inter alia*, business and personal relationships formed through contractual negotiations, conduct, and racketeering activities consistent with and in advancement of the Opioid Enterprise’s purpose of fraudulently and/or unlawfully expanding the prescription opioid market, and participation in and through both formal and informal coalitions and working groups.

815. The Defendants together formed an association-in-fact enterprise, the Opioid Enterprise, for the purpose of unlawfully increasing sales, revenues, and profits by lying to the DEA, failing to comply with their statutory and regulatory duties to identify and report suspicious orders, and failing to comply with their statutory and regulatory duties to perform adequate due diligence on red-flagged prescriptions and to refuse to fill those prescriptions without resolving red flags. Through their actions, the Defendants fraudulently increased the quotas set by the DEA that allowed them to collectively benefit from a greater pool of

prescription opioids to manufacture, distribute, and dispense throughout the United States, and to profit from the unrestricted and increasing sales of prescription opioids at every level of the supply chain—from manufacturing to dispensing. The Opioid Enterprise is an association-in-fact enterprise within the meaning of §1961.

816. The formation of the Opioid Enterprise’s Opioid Diversion Scheme began with contractual relationships between the Manufacturing and Marketing Defendants, who contract with Distributor and Pharmacy Defendants, as well as contractual relationships between Distributor and Pharmacy Defendants, and contractual relationships between Major PBMs and each of Manufacturing and Marketing Defendants and Pharmacy Defendants. These contractual relationships provided the interpersonal relationships that served as foundation for the Opioid Diversion Scheme.

817. The Defendants also formed interpersonal relationships through their participation in formal and informal trade associations, industry organizations, alliances, coalitions, and working groups. The factual record developed in the various tracks of this litigation provides a plethora of evidence that all Defendants, whether Manufacturer, Distributor, or Pharmacy, participated in Pharmaceutical Research and Manufacturers of America (“PhRMA”), Pain Care Forum, the Healthcare Distribution Alliance (“HDA”) or its predecessors, the National Association of Chain Drug Stores (“NACDS”), the Alliance to Prevent the Abuse of Medicines (“APAM”), the New Jersey Pharmaceutical Industry Working Group, the Anti-Diversion Industry Working Group (“ADIWG”), and the Midwest Controlled Substance Discussion Group (“MWDG”).

818. Each of the Defendants deepened their interpersonal relationships with each other through their membership in the entities and associations described above. Moreover, many

of the associations worked together on issues that affected the Defendants.

819. For example, PCF, HDA, and NACDS all worked together on the 2007 Industry Compliance Guidelines (ICGs) issued by the HDA on behalf of its members with the goal of creating a comprehensive strategy in response to increasing DEA enforcement. The ICGs were quickly withdrawn when the DEA used them as part of an enforcement action against Defendant Walgreens. HDA and NACDS worked closely with the HDA, noting that the pharmacy organizations appeared very anxious to help HDA persuade the DEA to change their current tactics with respect to license suspension. To that end, the HDA represented to the DEA that the ICGs would be promoted to its members and to allied trade associations such as NACDS and manufacturer associations like PhRMA, and that ICGs would serve as an industry standard. True to its word, HDA scheduled meetings with NACDS and PhRMA to roll out the ICGs that they had already been working on together.

820. The Defendants came together again in the early 2010s to discuss suspicious order monitoring, DEA actions, and thresholds. This time period was characterized by extensive sharing of information and coordination between the Defendants regarding their systems and procedures related to prescription opioids.

821. In addition to those initiatives that were coordinated by the Defendants' trade and industry organizations, the Defendants worked closely together. Manufacturers and Distributors worked together to ensure that there was no interruption in the supply chain, and the Major PBMs both worked with the Pharmacies and acted through their mail-order pharmacies to ensure that there was no interruption in the dispensing of prescription opioids.

822. In 2014 the PCF, HDA, NACDS, and APAM came together to coordinate a response to the Marino Bill including, specifically, to advance and support language that made

the bill more favorable to furthering the Opioid Diversion Scheme and undermined the effectiveness and enforcement ability of the DEA.

823. The Defendants were members of the PCF, HDA, NACDS, and APAM. Each of the Defendants is a member, participant, partner, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Claim.

824. These examples demonstrate that not only did the Defendants share a common purpose, but they worked together on issues that affected the Opioid Enterprise such as their ability to continue to profit from unlawful sales of prescription opioids.

825. At all relevant times, the Opioid Enterprise: (a) had an existence separate and distinct from each of the Defendants; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) was characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

826. Each Defendant member of the Opioid Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

827. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators and the American public by knowingly conducting or participating in the Opioid Diversion Scheme through a pattern of racketeering activity within the meaning of 18U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. §

1341 (mail fraud) and § 1343 (wire fraud), and involved the felonious manufacture, distribution, and dispensing of prescription opioids in violation of 18 U.S.C. §§ 841 and 843.

828. The Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Enterprise. The Defendants participated in the Opioid Diversion Scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

829. The Defendants also conducted and participated in the conduct of the affairs of the Opioid Enterprise through a pattern of racketeering activity by the felonious manufacture, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in § 102 of the CSA), punishable under any law of the United States.

830. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, Manufacturing and Marketing Defendants and Distributor Defendants (as registrants) violated 21 U.S.C. § 843(a)(4), which makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept, or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. §843(d)(1).

831. Each Defendant is a registrant as defined in the CSA. Their status as registrants

under the CSA requires that they maintain effective controls against diversion of controlled substances in Schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. §1301.74(b).

832. Each Defendant that is a pharmacy committed crimes punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 841 makes it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance except as authorized by Subchapter I of the CSA. A violation of § 841 in the case of controlled substances on Schedule II is punishable by not more than 20 years of imprisonment, or not less than 20 years imprisonment if death or seriously bodily injury results from the use of such substance. A violation of § 841 in the case of controlled substances on Schedule III is punishable by not more than 10 years imprisonment, or not less than 15 year imprisonment if death or seriously bodily injury results from the use of such substance. Similarly, a violation of § 841 in the case of controlled substances in Schedule IV is punishable by not more than 5 years imprisonment. All three violations of § 841 are felonies.

833. Each Pharmacy Defendant is a registrant as defined in the CSA. Their status as registrants imposes obligations on them to ensure that they only dispense “to the extent authorized by their registration and in conformity with the [CSA].” 21 U.S.C. § 822(b).

834. The Defendants’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via

U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, sell, and dispense the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

- b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, sell, and dispense the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

835. Controlled Substances Act Violations: The Defendants who are Distributor Defendants violated 21 U.S.C. § 823 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA. The Defendants who are Distributor and Pharmacy Defendants violated 21 U.S.C. § 841 by knowingly or intentionally possessing and dispensing controlled substances for reasons and purposes not authorized by the Controlled Substances Act.

836. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

837. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

838. The Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the manufacture, and distribution of suspicious orders or prescription opioids, and the dispensing of

illegitimate prescription opioids, that the Defendants were filling on a daily basis—leading to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

839. As members of the Opioid Enterprise, the Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent Opioid Diversion Scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

840. Indeed, for the Defendants' fraudulent Opioid Diversion Scheme to work, each one had to agree to implement similar tactics regarding the manufacturing, distributing, and dispensing of prescription opioids, while refusing to report suspicious orders and filling illegitimate prescriptions without conducting due diligence on red flags.

841. As described herein, the Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

842. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Enterprise and in furtherance of its fraudulent Opioid Diversion Scheme.

843. The pattern of racketeering activity alleged herein and the Opioid Enterprise are separate and distinct from each other. Likewise, the Defendants are distinct from the enterprise.

844. The pattern of racketeering activity alleged herein was continuing as of the date of Plaintiffs' original Complaint.

845. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Enterprise and its Opioid Diversion Scheme alleged herein depended upon secrecy.

846. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in the fraudulent Opioid Diversion Scheme and its unlawful course of conduct constituting a pattern of racketeering activity.

847. It was foreseeable to the Defendants that Plaintiffs would be harmed when they refused to report and halt suspicious orders, and when they filled illegitimate prescriptions without conducting due diligence to resolve red flags. Their violation of the duties imposed by the Controlled Substances Act and Code of Federal Regulations allowed the widespread oversupply of prescription opioids, causing the opioid epidemic that the CSA intended to prevent, and causing Plaintiffs to pay for prescription opioids and opioid-related treatment for which Plaintiff otherwise would not have paid.

848. It was foreseeable to the Defendants and members of the Opioid Enterprise that Plaintiffs would be harmed when they engaged in the fraudulent schemes that form the common purposes of the Opioid Enterprise and the pattern of racketeering activities alleged herein. Indeed, extracting money from commercial payors like Plaintiffs was a primary goal of Defendants' racketeering activities.

849. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering. Plaintiffs did not learn of its injury resulting from Defendants'

rackeering activities more than four years prior to the filing of Plaintiffs' original Complaint.

850. The Defendants' violations of law and their pattern of rackeering activity directly and proximately caused Plaintiffs' injury in their business and property. The Defendants' pattern of rackeering activity, including their refusal to identify, report, and halt suspicious orders of controlled substances, logically, substantially, and foreseeably cause an opioid epidemic. Plaintiffs were injured by the Defendants' pattern of rackeering activity and the opioid epidemic that they created.

851. The Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Defendants engaged in a scheme of deception that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.

852. The Defendants' predicate acts and pattern of rackeering activity were a cause of the opioid epidemic which has injured Plaintiffs in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid-addiction epidemic.

853. Specifically, Plaintiffs' injuries, as alleged throughout this Complaint, and expressly incorporated herein by reference, include:

- a. Emergency Medical care, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths without compensation or reimbursement;

- b. Emergency Medical treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by a mother during pregnancy without compensation or reimbursement;
- c. Emergency Medical treatment for hospital and/or urgent care emergency department visits and other treatment for opioid misuse, addiction, and/or overdose without compensation or reimbursement;
- d. Emergency Medical treatment for infections related to opioid misuse, addiction, and/or overdose without compensation or reimbursement;
- e. Emergency Medical treatment for hospitalizations related to the misuse, addiction, and/or overdose of opioids without compensation or reimbursement;
- f. Costs for providing opioid overdose reversal medication such as Naloxone Hydrochloride (Narcan) without compensation or reimbursement.
- g. Costs related to additional costs of hiring administrative staff in order to properly treat the increased number of individuals with Opioid Use Disorder seeking emergency medical treatment.
- h. Costs related to additional costs of hiring scribes needed to properly treat the increased number of individuals with

Opioid Use Disorder seeking emergency medical treatment.

854. Plaintiffs' injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial, and foreseeable cause of Plaintiffs' injuries.

855. Plaintiffs' injuries were directly caused by the Defendants' pattern of racketeering activities.

856. Plaintiffs are most directly harmed, and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

857. Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including:

- a. Actual damages and treble damages, including pre-suit and post-judgment interest;
- b. An order enjoining any further violations of RICO;
- c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;
- d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;
- e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;

- f. An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;
- g. An order enjoining any future marketing to vulnerable populations, including, but not limited to, persons over the age of 55, anyone under the age of 21, and veterans;
- h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning:(1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudo-addiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of function; (7) use of time-released opioids does not prevent addiction; (8) ADFs do not prevent opioid abuse; and (9)

that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

- i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;
- j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;
- k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;
- l. An order establishing a national foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;
- m. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious

- orders or diversion of opioids;
- n. An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;
 - o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Opioid Enterprise, including any interest in property associated with the Opioid Enterprise;
 - p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Opioid Enterprise identified in this Complaint, as the Court sees fit;
 - q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;
 - r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association, or enterprise named in the Complaint regarding the manufacture or distribution of opioids;
 - s. Forfeiture as deemed appropriate by the Court; and
 - t. Attorney's fees and all costs and expenses of suit.

THIRD CLAIM FOR RELIEF
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT18
U.S.C. 1962(d), et seq.
(Against all Manufacturing and Marketing Defendants)

858. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

859. Plaintiffs brings this Count against the Manufacturing and Marketing Defendants.

860. The Manufacturing and Marketing Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the Manufacturing and Marketing Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

861. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 793 through 819, and 950 through 1028 concerning the Opioid Diversion Enterprise, the Conduct of the Opioid Diversion Enterprise, and the Pattern of Racketeering Activity of the Opioid Diversion Enterprise.

862. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

863. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*,

556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'"
" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

864. For over a decade, the Manufacturing and Marketing Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Manufacturing and Marketing Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Manufacturing and Marketing Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "CSA"). The CSA restricts the Manufacturing and Marketing Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

865. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like

opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”

866. Finding it impossible to legally achieve their ever-increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined above) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the Manufacturing and Marketing Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Manufacturing and Marketing Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

867. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the Manufacturing and Marketing Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and deceive the public and federal and state regulators into believing that the Manufacturing and Marketing Defendants were faithfully fulfilling their statutory obligations. The Manufacturing and Marketing Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Manufacturing and Marketing Defendants' fraudulent

scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like Plaintiffs experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the Manufacturing and Marketing Defendants' misconduct violated Section 1962(c) and Plaintiffs are entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

868. Alternatively, the Manufacturing and Marketing Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Manufacturing and Marketing Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because It is a corporation and a legal entity.

869. On information and belief, each of the Manufacturing and Marketing Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

870. Each of the Manufacturing and Marketing Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and Manufacturers beyond the Manufacturing and Marketing Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Manufacturing and Marketing Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

871. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the Manufacturing and Marketing Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association in- fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion enterprise." The Manufacturing and Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs and the proposed Class members injury in their businesses, as described above in language expressly incorporated herein by reference.

872. Plaintiffs' and the proposed Class members' injuries were proximately caused by Defendants' racketeering activities. But for the Manufacturing and Marketing Defendants' conduct, Plaintiffs and the proposed Class members would not have incurred the monetary losses described above and expressly incorporated herein by reference.

873. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference The Manufacturing and Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' and the proposed Class members' injury in their businesses, as described above in language expressly incorporated herein by reference.

874. Plaintiffs bring this claim against all Manufacturing and Marketing Defendants. At all relevant times, the Manufacturing and Marketing Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the

Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

875. Plaintiffs' and the proposed Class members' injuries were directly caused by the Manufacturing and Marketing Defendants' racketeering activities.

876. Plaintiffs seek actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

FOURTH CLAIM FOR RELIEF
Negligence (Against All Defendants)

877. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege:

878. Defendants owed Plaintiffs a duty to not expose Plaintiffs to an unreasonable risk of harm.

879. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling, distributing, and/or dispensing opioids.

880. Defendants had a duty not to breach the standard of care established under state laws and the federal CSA and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

881. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, selling, and dispensing dangerously addictive drugs requires a high degree of care. Defendants' duty of care is independent of any contract between the parties. Their duty cannot be delegated.

882. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances. Defendants placed their profit motives above their legal duty and enabled, encouraged, and caused the over-prescribing and distribution of opioids.

883. Defendants breached their duty to Plaintiffs by, *inter alia*:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective and adequate controls against the diversion of opioids;
- c. Choosing not to effectively and adequately monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders;
- g. Distributing and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills”; and
- h. Failing to check for and conclusively resolve red flags of possible diversion before dispensing opioids.
- i. Through discovery, specific examples of pharmacies that placed excessive orders and particular orders that

Defendants should have reviewed or refused to fill will become available. This will include instances where the volume and/or frequency of orders were inconsistent with legitimate medical need, thus contributing to the illegal, secondary market.

884. In addition, Defendants engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the manufacturing, advertising, marketing, selling, distributing, and dispensing of their prescription opioids.

885. Manufacturing and Marketing Defendants also breached their duty to Plaintiffs by deceptively marketing opioids, including downplaying the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

886. Defendants were negligent by marketing, distributing, selling, and dispensing opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to Plaintiffs.

887. The method by which Defendants created this market was by marketing, distributing, selling, and dispensing opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, people suffering from opioid use disorder and addiction, juveniles, and others not permitted to use or possess prescription opioids.

888. A reasonably prudent opioid manufacturer, distributor, and dispenser should have anticipated an injury to Plaintiffs as a probable result of marketing, distributing, selling, and dispensing prescription opioids in this manner.

889. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to Plaintiffs as described herein.

890. Defendants had control over their conduct in the communities in which Plaintiffs' provide emergency medical services and treatment. Manufacturing and Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their shipments of opioids and their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, including the criteria and process they used to identify suspicious orders, whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

891. Manufacturing and Marketing Defendants' deceptive marketing of opioids and each Defendants' unique role in the closed opioid distribution system significantly contributed to the widespread use of opioids. Were it not for Defendants' conduct, the current public health crisis of prescription opioid and heroin overuse, abuse, and addiction would have been averted.

892. Because of the Manufacturing and Marketing Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

893. Defendants also misleadingly portrayed themselves as cooperating with law

enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

894. Defendants are in the business of manufacturing, marketing, distributing, and/or dispensing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because, *inter alia*, these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

895. Indeed, opioids are akin to medical-grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiffs—exactly as would be expected when medical-grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

896. Reasonably prudent manufacturers, distributors, and dispensers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon Independent Emergency Room Physicians. Indeed, it is a violation of numerous State Laws for distributors (including Manufacturing and Marketing Defendants registered as distributors) and a violation of federal law, 21 U.S.C. § 823, and 21 C.F.R. § 1301.74, for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. Indeed, the closed system of opioid distribution, whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

897. The Manufacturing and Marketing Defendants knew or should have known, that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs created an unreasonable risk of harm. Defendants' sales data, reports from sales representatives, and internal documents should have put them on notice that such harm was not only foreseeable but was actually occurring. Defendants nevertheless chose to deceptively withhold information about the dangers of opioids from physicians, like independent emergency room physician plaintiffs, patients, insurers, and the public.

898. Defendants also violated federal statutes and regulations, including the controlled substances laws, by, *inter alia*:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective and adequate controls against the diversion of opioids;
- c. Choosing not to effectively and adequately monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders;
- g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills"; and

- h. Failing to check for and conclusively resolve red flags of possible diversion before dispensing opioids.

899. As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered and will continue to suffer injuries, as alleged throughout this Complaint, including but not limited to:

- a. Emergency Medical care, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths without compensation or reimbursement;
- b. Emergency Medical treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by a mother during pregnancy without compensation or reimbursement;
- c. Emergency Medical treatment for hospital and/or urgent care emergency department visits and other treatment for opioid misuse, addiction, and/or overdose without compensation or reimbursement;
- d. Emergency Medical treatment for infections related to opioid misuse, addiction, and/or overdose without compensation or reimbursement;
- e. Emergency Medical treatment for hospitalizations related to the misuse, addiction, and/or overdose of opioids without compensation or reimbursement;

- f. Costs for providing opioid overdose reversal medication such as Naloxone Hydrochloride (Narcan) without compensation or reimbursement.
- g. Costs related to additional costs of hiring administrative staff in order to properly treat the increased number of individuals with Opioid Use Disorder seeking emergency medical treatment.
- h. Costs related to additional costs of hiring scribes needed to properly treat the increased number of individuals with Opioid Use Disorder seeking emergency medical treatment.

900. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, there is now a national opioid epidemic.

901. Defendants' alleged misconduct in this case is ongoing and persistent.

902. Plaintiffs have incurred expenditures as a direct result of Defendants' misconduct.

903. Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

904. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiffs.

905. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

906. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

FIFTH CLAIM FOR RELIEF
WANTONNESS, RECKLESSNESS, AND GROSS NEGLIGENCE

907. Plaintiffs, individually and on behalf of the putative Class, reallege and incorporate by reference paragraphs 1 through 792 as if stated fully herein.

908. Defendants' aforesaid acts and omissions were done and committed knowing that injury to Plaintiffs and the Class members would likely or probably result; were done or committed with a reckless or conscious disregard of the rights of Plaintiffs and the Class members; were done or committed without the exercise of even a slight degree of care; were done or committed with conscious indifference to the consequences; and/or constituted a substantial deviation from the standard of care applicable.

909. Each Defendant had duties to exercise reasonable, or due, care in marketing, promoting, selling, and distributing highly dangerous Schedule II opioid drugs.

910. Defendants' duties are set out as a matter of law, to monitor, report and prevent against diversion.

911. Each Defendant breached its aforesaid duties by its conduct previously specified herein; namely the false and misleading marketing promotion, sale and distribution of opioid drugs.

912. Manufacturer and Marketing Defendants breached their duties, as detailed above, when they:

- a. misrepresented that opioids improve function;
- b. misrepresented that opioids are safe and effective for long-term use;
- c. concealed the link between long-term use of opioids and addiction;
- d. misrepresented that addiction risk can be managed;
- e. masked the signs of addiction by calling them “pseudo-addiction”;
- f. falsely claimed withdrawal is easily managed;
- g. misrepresented or omitted the greater dangers from higher doses of opioids;
- h. deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs; and
- i. failing to monitor, report, and halt suspicious orders of opioids based on chargeback data.

913. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

914. The Pharmacy Defendants similarly breached their duty to exercise due diligence to monitor and report suspicious orders and avoid filling suspicious orders.

915. The PBM Defendants breached their duty in aiding the marketing and manufacturing defendants in exacerbating the opioid crisis, and failing to monitor, report and avoid filling suspicious orders.

916. Each Defendant owed its aforesaid duties to Plaintiffs and the members of the proposed Class because the injuries alleged herein were foreseeable by the Defendants.

917. The fact that Plaintiffs and the class they seek to represent would have to provide medical services for opioid addicted patients, would have to incur additional training and that these “pill seekers” would negatively rate physicians that refused to provide them opioids, was both the foreseeable and intended consequence of Defendants’ marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy, encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

918. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions at emergency rooms. It was also foreseeable to Defendants that Plaintiffs and the Class members would suffer the aforesaid monetary losses and damages because of the opioid epidemic.

919. Plaintiffs and the Class members incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, in the treatment of patients with opioid conditions. These patients would not have presented to Plaintiffs and the Class members, and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiffs’ and the Class members’ aforesaid monetary losses are the direct and proximate result of Defendants’ acts and omissions previously specified herein. Plaintiff and Class members also incurred other damages as identified above and incorporated herein.

920. As a direct and proximate result of Defendants' wantonness, recklessness, or gross negligence, Plaintiff and the Class members were monetarily damaged as aforesaid.

921. Plaintiffs seek compensatory and punitive damages, plus the costs of this action.

SIXTH CLAIM FOR RELIEF
COMMON LAW FRAUD

922. Plaintiffs, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1 through 792 as if stated fully herein.

923. As alleged herein, Manufacturer Defendants intentionally made false representations and concealed material facts about opioids, including but not limited to:

- a. misrepresented that opioids improve function;
- b. misrepresented that opioids are safe and effective for long-term use;
- c. concealed the link between long-term use of opioids and addiction;
- d. misrepresented that addiction risk can be managed;
- e. masked the signs of addiction by calling them “pseudo-addiction”;
- f. falsely claimed withdrawal is easily managed;
- g. misrepresented or omitted the greater dangers from higher doses of opioids;
- h. and deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

924. Manufacturer and Marketing Defendants made misrepresentations and failed to

disclose material facts to physicians and consumers throughout the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

925. The Pharmacy Defendants similarly breached their duty to exercise due diligence to monitor and report suspicious orders and avoid filling suspicious orders.

926. The PBM Defendants breached their duty in aiding the marketing and manufacturing defendants in exacerbating the opioid crisis, and failing to monitor, report and avoid filling suspicious orders.

927. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities.

928. Distributor Defendants made misrepresentations and failed to disclose material facts to authorities throughout the United States, to induce the prescription, administration and consumption of opioids as set forth herein.

929. Defendants' false representations and omissions were material, and were made and omitted intentionally or recklessly.

930. Defendants intended that physicians and consumers would rely upon their misrepresentations and omissions.

931. Physicians and consumers reasonably relied on Defendants' misrepresentations and omissions. Physicians prescribed and administered, and consumers purchased and

consumed, opioids as set forth herein.

932. Because of physicians' and consumers' reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs and the Class members have suffered monetary damages as aforesaid. Plaintiffs seek compensatory and punitive damages, plus the costs of this action.

933. Defendants' marketing of opioids caused Plaintiffs and the putative class he seeks to represent to diagnose, care for and treat opioid addicted patients who presented with opioid addicted symptoms. All of these medical services provided by Plaintiffs were caused by Defendants' fraudulent marketing and scheme. Defendants should be held responsible for all economic damages suffered by Plaintiffs and the putative class he seeks to represent. Plaintiffs are obligated to cover medically necessary and reasonably required care; he had no choice but to provide these services although often he was not paid or was paid substantially less than market rates.

934. The fact that Plaintiffs and the class they seek to represent would have to provide medical services for opioid addicted patients was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

935. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions in emergency rooms. It was also foreseeable to Defendants that

Plaintiffs and the Class members would suffer the aforesaid monetary losses and other damages because of the opioid epidemic. And by treating these patients, independent emergency room physicians suffered lost opportunity cost damages

936. Defendants' misrepresentations were material to, and influenced, the opioid-addicted patients presented to Plaintiffs and the class they seek to represent. In the first instance, Plaintiffs would not have been presented with, or required to diagnose, care and treat these opioid-addicted patients, but for Defendants' fraudulent and deceptive marketing. Second, Plaintiffs have demonstrated that Defendants' marketing is material by setting forth in detail Defendants' wrongful acts.

937. Plaintiffs and the members of the proposed Class seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action.

SEVENTH CLAIM FOR RELIEF

NUISANCE

938. Plaintiffs, individually and on behalf of the putative Class, reallege and incorporate by reference paragraphs 1 through 792 as if stated fully herein.

939. The nuisance is the over-saturation of opioids in the patient population of Plaintiffs and in the geographic area served by Plaintiffs for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

940. Defendants' misrepresentations and omissions regarding opioids as set forth above endanger or injure the property, health, safety and comfort of persons in Plaintiffs treatment population and have created opioid addiction in that population which created a nuisance

941. All Defendants substantially participated in nuisance-causing activities.

942. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

943. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

944. Defendants' activities unreasonably interfere with the economic rights of Plaintiffs.

945. The Defendants' interference with these rights of Plaintiffs is unreasonable because it:

- a. Has harmed and will continue to harm the public health services of and public peace of Plaintiffs;
- b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiffs serves;
- c. Is proscribed by statutes and regulation, including the CSA, and the consumer protection statute;
- d. Is of a continuing nature and it has produced long-lasting effects;
- e. Defendants have reason to know their conduct has a significant effect upon Plaintiffs; and
- f. Has inflicted substantial costs on Plaintiffs.

946. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

947. The resources of Plaintiffs are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

948. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

949. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiffs and in the geographic area served by Plaintiffs. Despite this Defendants did not abate the nuisance they created.

950. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm caused by Defendants' nuisance-causing activity, including, but not limited to, non-reimbursed and under reimbursed costs of providing medical services and treatment, increased training costs, reputational harm, in some cases lost employment, and lost opportunity costs described herein. In short, the Defendants created a mess, leaving it to the Plaintiffs and other Independent Emergency Room Physicians the costs of cleaning it up.

951. As a result of Defendants' actions, Plaintiffs have suffered a special injury, different from that suffered by the public at large by individual users and by governmental

entities, namely that Plaintiffs have provided uncompensated care for patients suffering from opioid related conditions.

952. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

953. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

EIGHTH CLAIM FOR RELIEF UNJUST ENRICHMENT

954. Plaintiffs repeats, realleges, and incorporates by reference the allegations set forth above in this Complaint, as though fully set forth herein.

955. Plaintiffs provided unreimbursed healthcare treatment to patients with opioid conditions that Defendants are responsible for creating. Plaintiffs thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

956. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact caused, Independent Emergency Room Physicians throughout the United States to provide unreimbursed healthcare treatment to patients with opioid conditions that Defendants were responsible for creating.

957. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

958. As described above, the benefit was received and retained under such
959. circumstances that it would be inequitable and unconscionable to permit
Defendants to avoid payment therefor.

960. Defendants have therefore been unjustly enriched.
961. By reason of the foregoing, Defendants must disgorge their unjustly acquired
962. profits and other monetary benefits resulting from its unlawful conduct and
provide restitution to the Plaintiffs.

NINTH CLAIM FOR RELIEF
NEGLIGENCE COMMON LAW FAILURE TO WARN
(Against the Marketing and Manufacturing Defendants)

963. Plaintiffs repeats, realleges, and incorporates by reference the allegations set
forth above in this Complaint, as though fully set forth herein.

964. Count IX is brought by Plaintiffs on behalf of themselves and the putative class.

965. Manufacturing and Marketing Defendants knew that opioids were highly
addictive and inappropriate and unsafe for the treatment of chronic pain. Manufacturing and
Marketing Defendants had such actual and unequal knowledge of the risks and harms likely to
result from the long-term prescription and knew or should have known that harm would result
from such use.

966. To expand the market for opioids, however, Manufacturing and Marketing
Defendants engaged in a misinformation campaign to alter public perception of opioids, and
deceive doctors, federal regulators, and the public about their addictive and unsafe qualities.
Manufacturing and Marketing Defendants perpetrated virtually uniform misrepresentations,
concealments, and material omissions regarding (a) the safety and efficacy of opioids for the

treatment of chronic pain and (b) their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

967. Because of barriers to prescribing opioids associated with their regulation as controlled substances, Manufacturing and Marketing Defendants knew doctors would not treat patients with common chronic pain complaints with opioids, and insurers and other third-party payors would not cover such treatment, unless they were persuaded that opioids had real benefits and minimal risks.

968. Accordingly, Manufacturing and Marketing Defendants spent millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

969. Manufacturing and Marketing Defendants did not disclose to prescribers, patients, third-party payors, or the public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable, though providing such warnings and accurate information would not have imposed a burden. Rather, each Manufacturing Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. Defendants failed to warn doctors of dangers of opioids.

970. Manufacturing and Marketing Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

971. Plaintiffs and the Class thus, both directly and indirectly, relied on the representations as to the efficacy and safety of opioid drugs for the treatment of chronic pain as

promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of opioid drugs' efficacy and safety were based, Plaintiffs and the Class, as well as other third-party payors and members of the medical community and public, were obligated to rely on Defendants' representations about opioids. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of opioids for chronic pain and ensure that they were authorized for coverage and broadly distributed.

972. Manufacturing and Marketing Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels, including through their financial incentives and information sharing arrangements with other Defendants. Manufacturing and Marketing Defendants also knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed. Manufacturing and Marketing Defendants further knew that widespread opioid addiction and abuse was harmful to the individuals consuming opioids, their friends, families, and communities, and those, like Plaintiffs, responsible for treating patients with opioid misuse associated with opioid addiction and abuse among their insureds.

973. Nonetheless, Manufacturing and Marketing Defendants unreasonably persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids. In doing so, Manufacturing and Marketing Defendants failed to take reasonable precautions in presenting opioids to the public.

974. By failing to adequately warn the public, including prescribing doctors, and Plaintiffs, of the dangers of opioids, Manufacturing and Marketing Defendants' conduct directly injured Plaintiffs and the Class.

975. As a consequence of the Manufacturing and Marketing Defendants' breach of their common law duty to warn, Plaintiffs and the Class have suffered damages and will continue to suffer damages.

TENTH CLAIM FOR RELIEF
VIOLATION OF SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT § 39-5-140 et. seq.

976. Plaintiffs repeats, realleges, and incorporates by reference the allegations set forth above in this Complaint, as though fully set forth herein and is brought against all Defendants

977. This cause of action is brought pursuant to South Carolina § 39-5-10 to -560. which is known as the Unfair Trade Practices Act (UTPA).

978. The intent of the UTPA is to provide recourse when there is an unfair or deceptive act or practice in the conduct of any trade or commerce which injuriously affects the people of South Carolina.

979. Section 39-5-140(a) creates a private right of action in favor of "[a]ny person who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of an unfair or deceptive method, act or practice declared unlawful by § 39-5-20.

980. Plaintiffs are "person[s]" within the meaning of § 39-5-10.

981. All Defendants engaged in "[t]rade or commerce" within the meaning of S. C. Code Ann. § 39-5-10(b) (1976).

982. During the relevant period and as detailed further herein, the Marketing and Manufacturing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the UTPA by actively promoting and marketing the use of opioids for

indications not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.

983. Each of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. § 1301.74(b). The CSA defines "registrant" as any person who is registered pursuant to 21 U.S.C § 823. 21 C.F.R. § 1300.02(b). Section 823(a)-(b) requires manufacturers and distributors of controlled substances Schedule II to register.

984. Defendants' unfair or deceptive acts or practices in violation of the UTPA negatively affected the public interest, and are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will.

985. Defendants' actions were willful and knowing violations of the UTPA § 39-5-20.

986. As a direct and proximate result of Defendants' violations of the UTPA, Plaintiffs have suffered and continues to suffer injury-in-fact and actual damages as identified herein and incorporated by reference.

987. Defendants, individually and acting through acting through their employees and agents, and in concert with each other, knowingly advertised and made material misrepresentations and omissions of facts to Plaintiffs and the putative class to induce Plaintiffs and the punitive class to prescribe and have patients purchase, administer, and consume opioids as set forth in detail above.

988. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

989. Defendants intended that Plaintiffs, physicians, patients, and/or others would rely on their misrepresentations and omissions.

990. Plaintiffs, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

991. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

992. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs and the class, suffered actual pecuniary damage.

993. Defendants' conduct was willful, knowing, wanton, and malicious and was directed at the public generally and violation of the UTPA.

994. Plaintiffs are entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs individually and on behalf of all others similarly situated, ask that the Court:

- (a) Certify the Class proposed herein;
- (b) Appoint Plaintiffs as representative of the Class;
- (c) Appoint Plaintiffs' counsel as attorney for the Class;
- (d) Enter judgment awarding Plaintiffs and the Class members monetary damages, compensatory in nature, on their negligence claim;

- (e) Enter judgment awarding Plaintiffs and the Class members monetary damages, compensatory and punitive, on their claims for wanton, reckless, and grossly negligent conduct, and on their claims for fraud;
- (f) Enter judgment awarding Plaintiffs and the Class members treble damages on their RICO claims;
- (g) Award Plaintiffs and the class members prejudgment interest and post-judgment interest as provided by law;
- (h) Award Plaintiffs and the Class members a reasonable attorney's fee and costs; and
- (i) Provide such further relief as may be just and proper.

JURY DEMAND

Plaintiffs, individually and on behalf of the Class members, demand a trial by jury on all issues so triable.

Respectfully Submitted,

DATED: December 19, 2024

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